EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION,	Master File No. 2:12-MD-02327 MDL 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

THIS DOCUMENT RELATES TO:
Wave 4 Cases

GENERAL RE: TVT MATTER

DEPOSITION OF OLGA RAMM, M.D.

Oakland, California

Friday, March 17, 2017

Volume I

REPORTED BY:
REBECCA L. ROMANO, RPR, CSR No. 12546

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CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION,

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DEPOSITION OF OLGA RAMM, M.D., taken on behalf of the Plaintiff, at Oakland Marriott City Center, 1001 Broadway, Conference Room 212, Oakland, California, commencing at 9:34 a.m., Friday, March 17, 2017 before Rebecca L. Romano, Certified Shorthand Reporter No. 12546

APPEARANCES OF COUNSEL

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I N D E X

E X H I B I T S

Oakland, California, March 17, 2017
9:34 a.m.
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OLGA RAMM, M.D.,
having been administered an oath, was examined and testified as follows:

EXAMINATION

BY MS. LIU:

Q. Good morning, Doctor.
A. Good morning.
Q. For the record, could you please state your full name.
A. Olga Ramm.
Q. And how do you spell Ramm?
A. R-A-M-M.
Q. Thank you, Doctor.

Doctor, we met off the record, but officially my name is Mary Liu. I represent the plaintiffs in this case.

A. Nice to meet you.
Q. Doctor, have you ever been deposed before?
A. I have been deposed in -- in residency or after residency about a case pertaining to residency.
Q. And what year was that?

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A. I think it would have been 2013 or 2014. I can't exactly recall.
Q. And you have been deposed one time?
A. Yes.
Q. Just to go over the rules a little bit briefly here.
If you need to take a break, just let me know. The only thing that I ask is that if I have a question pending, for you to answer that question prior to taking a break.
A. Sure.
Q. If you don't understand my question, could you please ask me to clarify?
A. Uh-huh.
Q. If you answer, I'm going to assume that you understood my question.
Okay?
A. Okay.
Q. The other thing is this is a question/answer session. So we need to make sure that we don't talk over each other for the court reporter's sake because she's not going to be able to take down what we both say at the same time.
And also, I see that you are nodding your head, and you have to answer verbally so that she's

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able to take down your answers. So a "yes," "no" rather than "huh-huh," "uh-huh" because that's very hard to translate on the record.
Okay?
A. Understood.
Q. Thank you, Doctor.
If there are some other things that come up, I will let you know as well.
A. Sounds good.
Q. Doctor, I am handing you what I have marked as Exhibit 2.
(Exhibit 2 was marked for identification by the court reporter and is attached hereto.)
Q. (By Ms. Liu) Doctor, have you seen this before?
A. Yes.
Q. Okay. And, Doctor, if you will look on page 7, you see Schedule A.
Did you take a look at Schedule A prior to today?
A. I did.
Q. I know that you have provided an invoice via email this morning and six separate thumb drives, correct?
A. Yes.

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Q. And these are in response to Schedule A?
A. Correct.
Q. Do you know what's on these thumb drives?
A. So the thumb drives contain a combination of company documents, studies pertaining to my general report, and stress incontinence surgery, in general, as well as pelvic surgery and any relevant studies that were cited or used in preparation of the general report.
Q. Did you put together the thumb drives?
A. I did not put together the thumb drives.
Q. Do you know how they were put together?
A. They were put together by Butler Snell.
Q. Did you send them the information to put on it? Do you know how the information got on there?
MR. SNELL: Objection to form. Asked and answered. Compound.
THE DEPONENT: So some of the information I cited in my general report as a result of my research and -- and in complying it. Some of the information was background studies that are just widely read on the subject. And some of it was studies -- you know, company documents that, obviously, I wouldn't have been privy to that were sent to me for review.
Q. (By Ms. Liu) Doctor, is this the first time

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you have ever been asked to be an expert?
A. It is.
Q. Have you been a consultant for any medical device company in the past?
A. No.
MR. SNELL: Counsel, can I ask a question. Are you done with the materials?
MS. LIU: No.
MR. SNELL: Okay. Because I just want the record to reflect the doctor has brought numerous hard-copy materials as well. I didn't want there to be a misrepresentation on the record that all there was was thumb drives.
MS. LIU: That's fine.
MR. SNELL: Okay.
Q. (By Ms. Liu) Doctor, when did Ethicon first contact you to become an expert witness?
A. In 2016.
Q. What month?
A. Let me think.
I -- I don't recall the exact month. It would have been sometime over the summer, I believe.
Q. And when did you decide to become an expert for Ethicon?
A. Shortly thereafter.

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Q. Why did you decide to become an expert for Ethicon?
A. Well, as you know, there's been a lot of litigation and just a lot of legal scrutiny around mid-urethral slings, the TVT specifically. I used the TVT in my practice as the first-line surgical approach to the treatment of stress urinary incontinence in women who have no contraindications to it. And, whereas, I have seen other slings go off the market, I would hate to see that happen to the TVT. I think it would be a disservice to women.
Q. Doctor, you mentioned previously that you had been deposed one time.
Was that a malpractice case?
A. It was. I wasn't named it in. I was one of the witnesses.
MS. LIU: Can we go off the record.
(Recess taken.)
MS. LIU: Back on.
Just -- just for the record, Exhibit 1 is marked as the doctor's TVT general report.
(Exhibit 1 was marked for identification by the court reporter and is attached hereto.)
MR. SNELL: Thank you, Counsel.
Q. (By Ms. Liu) Doctor, I was talking to you

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earlier about the malpractice suit in which you were deposed.
You mentioned that you were not named in it, correct?
A. Correct.
Q. Was the case involving any kind of medical device?
A. It was an obstetrical case.
Q. Doctor, your counsel just brought in the invoice -- your invoice, which I have marked as Exhibit 3.
(Exhibit 3 was marked for identification by the court reporter and is attached hereto.)
Q. (By Ms. Liu) Can you take a look at that?
MR. SNELL: I'm just going to object to the predicate. I'm not Dr. Ramm's counsel. I represent Ethicon and Johnson & Johnson.
MS. LIU: Thank you.
MR. SNELL: Just so that that is clear.
Q. (By Ms. Liu) Doctor, do you recognize that as your invoice?
A. I do.
Q. Did you prepare that?
A. I did.
Q. And I believe it states that you have spent

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33-1/2 hours; is that correct?
A. Between November 2016 and January 31st, 2017, yes.
Q. And, Doctor, how did you calculate the 33-1/2 hours?
A. So I just kept a daily log of the time that I spent working on the general report, kind of on a day-by-day basis, and then I searched my calendar and added it all up.
Q. Doctor, do you have that daily log still?
A. I could probably find it in my calendar.
MS. LIU: Counsel, I would like to have the daily log produced, please.
MR. SNELL: I will take it under advisement.
Q. (By Ms. Liu) Doctor, in drafting your report, how much time would you -- would you be able to allocate to doing research or actually doing the drafting out of your 33-1/2 hours?
MR. SNELL: Object to form. Compound.
Go ahead.
THE DEPONENT: You know, it's hard for me to say that because oftentimes I would be reading as I wrote the report. So it's hard to separate those out.
Q. (By Ms. Liu) And, Doctor, did you meet with Mr. Snell or any other attorney that represents Ethicon

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in preparation for your deposition today?
A. I did.
Q. When?
A. Yesterday.
Q. And how many -- how long?
A. About 9:30 to 5:00, with a lunch break.
Q. And who was the person who contacted you to become an expert for Ethicon?
A. Mr. Snell.
Q. Have you had any contact with any other attorney besides Mr. Snell?
A. I believe I had a telephone call with -- with another attorney, and I -- I don't recall her last name. I'm sorry.
Q. Do you know the first name?
A. I believe her first name was Sherry.
Q. And, Doctor, you mentioned that you were reading a lot while drafting your report.
Doctor, how did you get the literature that you used in your report?
A. Well, some of the literature was previously known to me, obviously, as a result of my training. I also performed PubMed searches and MEDLINE searches.
Q. Doctor, did Butler Snell provide you with literature?

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A. They provided me with literature, some -- you know, you see the binders.
Q. Do you know how they provided you those literature?
MR. SNELL: Object to form.
THE DEPONENT: They FedEx'd it to me.
Q. (By Ms. Liu) Do you know how they determined which articles or which piece -- which studies to send to you?
A. So doing my own review of the studies that they sent to me, it was -- it was pretty clear that it was a comprehensive list of studies that pertain to the TVT, but also stress incontinence surgery, in general. So there are studies that involve the Burch fascial slings, as well as company documents.
Q. Doctor, I want to turn to just a little bit about your background with TVT.
A. Okay.
Q. How many TVT implants have you performed?
A. So, roughly, 1400. I think it states that in my general report.
Q. And what years did you perform these TVT implants?
A. I started performing them in my residency. My residency was from 2005 to 2009. And then,

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obviously, did a much higher volume in fellowship. And, thereafter, I still performed the implants.
Q. Now, in your report you mention both performing the TVT retropubic original as well as the EXACT sling; is that correct?
A. Uh-huh.
MR. SNELL: You have to say "yes" or "no."
THE DEPONENT: Yes. Sorry.
MR. SNELL: That's okay.
Q. (By Ms. Liu) Doctor, currently, today, do you use the TVT EXACT?
A. Currently, I'm using the original TVT.
Q. And when did you use the EXACT?
A. I used the EXACT in fellowship and early on in my practice at Kaiser Permanente.
Q. And why did you stop using the EXACT?
A. Well, I worked in the -- I work in the context of a managed-care organization and there are preferred products. And I didn't see a clinical difference in the performance of the original TVT and the TVT EXACT, but the original TVT is actually substantially cheaper. And so that is the preferred product for Kaiser Permanente and that's why I used primarily the TVT original.
Q. And, Doctor, do you have a role in making

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that decision with Kaiser?
A. I am not on the contract negotiation team, but I can make recommendations. So if I felt that one sling was substantially better than the other, certainly I would voice that opinion and that opinion would be taken under heavy consideration by the contract team.
Q. And, Doctor, have you used any other slings in the past?
A. I have used the Boston Scientific Advantage and Advantage Fit in my training.
Q. Any others?
A. In residency, we worked with private physicians who may have used other slings. So on occasion, I may have participated in a case, but -- but not -- not when I was the independent surgeon.
Q. Doctor, you mentioned that you had implanted 1400 TVT slings. Now, you have mentioned that that started in residency.
In residency, were you the doctor who actually implanted the sling or were you assisting a doctor?
A. So in order to log the case, you have to perform as -- when you are the resident and you have to report this to the ACGME, you have to perform at least

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50 percent of the case. So whereas I was being supervised by an attending physician, I performed more than 50 percent of the procedure.
Q. And when you say you performed more than 50 percent of the procedure, does that -- strike that.
What portion of the procedure did you perform in the more than 50 percent that you just described?
A. Okay. So, generally, I would make the incision. Prior to the incision, I would do all of the requisite injections. I would do the dissection of the TVT tunnels, and usually I would be the one to pass the dominant side. So for me, as a right-handed surgeon, that's the patient's right side.
And then, generally, you know, depending on the case, especially if it was earlier in residency, the attending surgeon would pass the nondominant side, and then I would perform the cystoscopy. And earlier on in residency -- and, actually, usually in residency, it was the attending physician who would tension the sling. And then I would close the incision.
Q. So the tensioning -- during residency, the tensioning was performed by the attending physician, correct?
A. Yeah, with me assisting right there next to them.

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Q. And when did you start performing TVT implantations on your own without an attending surgeon?
A. In fellowship.
Q. And what year was that?
A. So fellowship was 2009 through 2012.
Q. And how many TVT slings would you say you would have implanted starting from fellowship to present day?
A. So I think in my report I say I did about 750 cases in fellowship and approximately 600 since then. So what is that, 13- --
Q. 1350?
A. Yeah.
Q. And you mentioned 1400.
So you only did 50 cases during residency?
MR. SNELL: Object. Misstates.
THE DEPONENT: It's an estimate. But, generally, residency is comprised of, at most, four urogynecology rotations. So that would make sense.
Q. (By Ms. Liu) And, Doctor, have you done a registry of your own sling patients?
A. What do you mean by "registry"?
Q. Well, how do you keep track of them?
A. So, generally, postoperatively, I have the patients follow up between two and four weeks

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postoperatively; then at three months and then again at one year.
The sling implants are all entered into a Kaiser Permanente database that's part of the electronic medical record. I keep my own log of surgical cases and, every couple of years, go back to -- through the charts to see whether there are any new developments that are -- that are related to the outcomes of those cases.
And we also -- within Kaiser northern California, we have a network of physicians who are pelvic reconstructive surgeons, so they are the ones that are performing these types of cases. So if -- you know, if a patient moves away, or whatever, but they stay with the same insurance provider, I will -- I will have follow-up that way.
Q. And, Doctor, you mentioned that you see your patients at two weeks, four weeks, three months and a year?
A. Between two and four weeks, so that's one time.
Q. Okay. So between two and four weeks, you have your initial postop, and then you have another postop appointment at three months?
A. Correct.

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Q. And then a follow-up appointment at the one-year mark, correct?
A. Correct.
Q. And then what happens after the one-year mark?
A. So after the one-year mark, it kind of depends on the patient. Some patients who are particularly attached come in yearly. And then there's some patients who prefer not to come in for an in-person visit. Sometimes I will follow up with those patients via an email.
Q. And, Doctor, do you have patients that don't follow up at the one-year mark?
MR. SNELL: Object to form.
THE DEPONENT: I am sure there are some patients that don't, but we have a pretty decent system to -- I would say the majority certainly do.
Q. (By Ms. Liu) And do you do anything proactively to keep track of whether or not patients show up for their follow-up appointments?
A. Yeah. So, actually, at their three-month postoperative visit, I send a secure message to my care team with a reminder that they should come back -- you know, let's say their one-year postop will be in August, so I send a message to my care team to say,

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Please schedule postop visit in August. And so then they contact the patient. And if -- if the patient can't be contacted, I hear back that way.
Q. And, Doctor, after the one-year mark, if a patient doesn't come back to see you, you don't know what happens to that patient; is that correct?
MR. SNELL: Object to form.
THE DEPONENT: So if a patient stays within the Kaiser Permanente system, if they come back for something related to their urogynecologic condition, I would more likely than not know that because it's a small group of colleagues of mine. And so people would either contact me or would cc me the chart at the end of the encounter.
Q. (By Ms. Liu) Doctor, if the patient leaves a Kaiser Permanente group, then you would not have a -- any notice as to any kind of problems that might arise after that; is that correct?
MR. SNELL: Object to form.
THE DEPONENT: I suppose that's possible, yes.
Q. (By Ms. Liu) You mentioned that you have a log of your surgical cases.
How often do you go and find patients that had been lost?

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MR. SNELL: Object to form.
THE DEPONENT: That have been -- what do you mean by "lost"?
Q. (By Ms. Liu) That haven't followed up with you after the year mark.
MR. SNELL: Same objection.
THE DEPONENT: Okay. I'm sorry. I'm not sure I quite understand the question.
Q. (By Ms. Liu) Okay. Let me try to break it up a little.
A. Sure.
Q. You mentioned that you do have a log of all your surgical cases, correct?
A. Yes.
Q. So after a year, if a patient doesn't come back to see you and you are not getting updates about that patient, do you ever go and try to look through your log and try to find these patients and see what's going on with them?
MR. SNELL: Object to form.
THE DEPONENT: So the expected follow-up is at one year postoperatively. Do I go through, you know, at three-, four-, five-year intervals to see where that patient is and try to contact the patient? No, I don't do that.

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Q. (By Ms. Liu) And, Doctor, currently, today, you stated that you use the TVT original.
Do you use the one that is mechanically cut or the one that is laser cut?
A. Mechanically cut.
Q. And why do you use the mechanically cut one?
A. So, again, I don't think that there is any difference in the clinical outcomes or ease of implant, but the mechanically cut TVT is significantly cheaper.
Q. Than the laser cut?
A. Than the laser cut.
Q. Doctor, have you taken the mechanically cut TVT sling out of the sheath and felt it?
A. Yes. I have patients feel it preoperatively.
Q. And, Doctor, have you seen particles come loose from the mechanically cut TVT?
MR. SNELL: Object to form.
THE DEPONENT: I have seen some particles come off of the TVT sling when I cut the -- when I cut the mesh at the suprapubic skin site.
Q. (By Ms. Liu) And these particles would be blue?
A. Yeah.
Q. And, Doctor, let's talk a little bit about the TVT sling coming out of the kit.

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Does your OR nurse open the package for you?
A. Generally. Uh-huh.
Q. When you take -- strike that.
When the kit is on your --
A. Table.
Q. -- table, yeah -- what does it look like coming out of the package?
A. So it's -- the sling itself is encased in a plastic sheath attached to the two metal trocars.
Q. So the sling is actually attached to the metal trocars, correct?
A. Uh-huh.
Q. And then there is a handle that you screw on to each side to pass the trocars; is that correct?
A. Right.
Q. Is the handle reusable?
A. It is.
Q. So do you know how the metal trocars are attached to the sling?
A. Yeah, they are bonded to the -- the sling is bonded to the trocar.
Q. And, Doctor, have you ever taken the sling off the trocar prior to implantation?
A. So for -- for teaching purposes with residents, but I didn't then go on to implant that

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sling, so, no.
Q. Okay. So it's not meant to be taken off the trocars for you to implant separately without those trocars; is that correct?
A. That's correct.
Q. And that would not be within your standard of care to do so; is that correct?
A. To implant the TVT without the use of the trocars --
Q. Correct.
A. -- is that what you are asking me?
Q. That is what I'm asking.
A. I don't -- I don't generally do that; although, I don't know that there's a standard of care around the use or nonuse of trocars.
Q. And, Doctor, you mentioned that this trocar was bonded to the mesh, correct?
A. I did.
Q. So it's not meant for you to take it apart prior to implanting it in a woman, correct?
A. It's not meant to be taken apart, no.
Q. Okay. And, Doctor, let's talk a little bit about the trocar.
I know in your report you mention that it is a 5-millimeter trocar; is that correct?

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A. Yes.
Q. I know in your report you also mention that it was a 1-centimeter sling. But in a different part of your report, you mention that it is an 11-millimeter sling.
Were you just doing an estimate for the centimeter?
MR. SNELL: Object to form.
THE DEPONENT: So it's 11 millimeters in width.
Q. (By Ms. Liu) So let's talk about this implantation, then.
Doctor, the trocar is 5 millimeters and it's tubular, correct?
A. Yes. So in a cross-section it is round.
Q. So it is a 5-millimeter diameter?
A. Right.
Q. Now, you are passing an 11-millimeter flat mesh through that space that you have created with the 5-millimeter trocar; is that correct?
A. So you are passing the mesh through tissue, but there's no space, per se, that is created by the trocar itself. It's not like the trocar is there to create a passageway or a canal or a tunnel. Rather, it's there to guide the path.

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So you could actually use, you know, a very small needle rather than a 5-millimeter trocar. You don't need -- yeah, you don't need the trocar to be the same shape or size or width as the mesh itself.
Q. Now, the TVT retropubic is original -- sorry -- is supposed to be placed behind the pubic rami; is that correct?
A. Yes.
Q. So it passes through underneath the urethra in the dissection that you've made, correct?
A. So in the midline it sits under the mid-urethra, and then, through the tunnels, it passes through the under-pelvic connective tissue around the urogenital diaphragm and the retropubic space and then exits through the rectus tendon as it inserts on the pubic bone. And then it makes its way through the fatty tissue under the skin and then through the skin, ultimately.
Q. And, Doctor, that -- that retropubic space that you are talking about, it's not an open space, is it?
MR. SNELL: Object to form.
THE DEPONENT: So it's a potential space.
Q. (By Ms. Liu) And it is a space that is created by the surgeon to be -- to implant a product;

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is that correct?
A. Actually, the retropubic space is not developed with the implantation of the TVT. That's what makes it minimally invasive. That's what also decreases your risk of bleeding, right? So the retropubic space is a space that you would develop with a Burch procedure, for example, where you actually have to physically go in there and suture in that space.
It's also a space that you would have to develop with the passage of a fascial sling, you know, where you -- where you are actually entering abdominally and then making your way from above into the vagina.
But with the TVT, you don't have to develop the retropubic space. It pass -- the trocar and the mesh that follows it passes through this space without having to expand it.
Q. Now, Doctor, the mesh is supposed to lay flat; is that correct?
A. The mesh should be flat under the mid-urethra.
Q. And how do you ensure that the mesh is flat in the retropubic space and in the layers of fat underneath the skin and the fascia?
MR. SNELL: Form objection.

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THE DEPONENT: Well, I think that's a two-part question.
So to answer the question directly, the mesh is encased in the plastic sheath that ensures that the mesh stays flat, right?
The second part to that question is actually -- it is -- it's important to have the mesh flat in the areas where it comes into contact with the periurethral tissues. But you could very easily make the argument that it doesn't need to be completely flat in the subcutaneous tissues, like, for example, in the adipose tissue under the skin.
Q. (By Ms. Liu) So now, Doctor, do you know what the weight of the mesh is prior to implantation?
A. Do you mean per-centimeter surface area --
Q. Yes. Per-centimeter squared, what the gram amount is.
A. I would have to look that up. I don't recall off the top of my head.
Q. I will represent to you that it's 100 grams per centimeter squared.
A. Okay.
Q. Does that sound approximately right to you?
A. Per centimeter squared?
MR. SNELL: I will object. Hold on. I have

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to object as to the foundation as to that exact number.
But go ahead.
THE DEPONENT: Per --
Q. (By Ms. Liu) Per centimeter.
A. -- squared of surface area, 100 grams. No, I would disagree with that.
Q. That's fine. You can look that up later.
A. Okay.
Q. Let me ask you. If -- if the mesh is not flat in the retropubic space when it -- when it passes through, it would fold; is that correct?
MR. SNELL: Object. Foundation.
THE DEPONENT: Again, I think that we could make all kinds of conjectures about what the mesh would do if it weren't flat when it passes through the retropubic space, but I have no reason to believe that it's not flat when it passes through the retropubic space. The plastic sheath flattens the mesh and keeps it in that orientation when it's passing through the retropubic space.
Does that make sense?
Q. (By Ms. Liu) And, Doctor, you pull the sheath off after implantation; is that correct?
A. Yeah.
Q. The sheath doesn't stay in; is that correct?

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A. Right. The sheath does not stay in the patient once the procedure is done.
Q. Now, are you claiming that the mesh, after implantation, is so stiff that it wouldn't curl in a 5-millimeter space that is being created?
MR. SNELL: Object. Form. And totally misstates.
Go ahead.
THE DEPONENT: So, again, there's -- there's no 5-millimeter space that is created, right? That's -- that's an erroneous premise to this.
The mesh is placed inside the plastic sheath. And when the plastic sheath is pulled up, then there's sort of a friction effect that keeps the mesh in place along the edges of the mesh. So the tissue attaches to those. And then, over time, tissue ingrowth into the pores of the mesh keeps it in the orientation at which it was originally placed.
Q. (By Ms. Liu) And, Doctor, how long does it take for the tissue ingrowth process to complete?
A. Well, to answer that question, we have to look at wound healing and scar tissue remodeling. So that's not a linear process, right?
That process is more rapid in the beginning. So within the first four weeks, a large portion of that

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ingrowth has occurred, but scar tissue remodeling goes on over the course of months through the first year after implantation.
And that's not unique to the TVT. That's true of a Cesarean delivery incision or -- or, really, any kind of wound.
Q. So, Doctor, in the first four weeks where you are describing the -- the more rapid tissue ingrowth, during -- during the time that the patient is healing in those first four weeks, the patient is not laying in the lithotomy position the whole four weeks; is that correct?
A. That's correct.
Q. So after you finish the procedure, the woman's legs come down, correct?
A. Yes.
Q. And then the patient is able to move; is that correct?
A. Yeah. They are encouraged to ambulate, to perform their usual daily activities, barring any, you know, excessively heavy lifting and exertion.
Q. So prior to the tissue -- the full tissue ingrowth, when the patient is moving around like normal, how do you ensure that the mesh that's been placed there has not curled or is not rolling?

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A. Because the mesh has been -- has been secured in place with surface tension, and if the -- if there were more pressure in that area, then the mesh would most likely be more flattened out. It wouldn't curl in response to that.
Q. And, Doctor, have you -- have you removed mesh?
A. I have removed mesh.
Q. So you perform revision procedures, correct?
A. That's correct.
Q. How many times?
MR. SNELL: Object to form. Vague, mesh.
Are you talking just TVT, or are you -- any and all mesh?
Q. (By Ms. Liu) Let's just start with TVT.
A. So are you asking specifically in my practice or ever?
Q. Ever.
A. Ever. I would say I have probably done somewhere between 20 and 30 revision procedures. And that includes in fellowship, as we were a ordinary-care center.
Q. And this is 20 to 30 sling revisions?
A. Sling revisions.
Q. Have you done revisions dealing with pelvic

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organ prolapse mesh?
A. I have.
Q. How many?
A. You know, maybe a -- a third of that number.
Q. So eight to ten?
A. Eight to ten.
Q. So eight to ten pelvic organ prolapse mesh revisions, correct?
So in the sling revisions, in the 20 to 30 that you have performed, have you gone into the retropubic space via an abdominal incision?
A. So that's generally not necessary. I recall having to do that in only one case. But, generally, that's not the problem area and that's not what is required.
Q. So, Doctor, in those 20 to 30 revisions, you haven't seen what the sling looks like in the retropubic space, have you?
MR. SNELL: Object. Form.
THE DEPONENT: I haven't had reason to look in the retropubic space and dissect the sling out. That would be more than necessitated by the -- the cause for the sling revision.
Q. (By Ms. Liu) And, Doctor, have you done any ultrasounds to measure the width of the sling in the

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retropubic space?
A. I have done ultrasounds to measure the width of the sling in the retropubic space.
Q. How many times?
A. So the BK ultrasound has a 3D probe that's a linear probe that -- that can be used for imaging mesh. And so when I was learning to use that ultrasound, I would do intraoperative and then 12-week postoperative ultrasounds to ascertain the location of the mesh and whether it looked the same before versus at the postop visit and it did.
Q. Did you measure the --
MR. SNELL: You said -- what was the spelling of that? BK ultrasound?
THE DEPONENT: B-K.
Q. (By Ms. Liu) And did you measure the thickness of the mesh during these ultrasounds?
A. By "thickness," do you mean width?
Q. No. By "thickness," I mean you have got the width, you have got the length and you have got the thickness of it, so from, you know, one side of where the pores are to the other side.
MR. SNELL: Object. Form.
THE DEPONENT: So, generally, on ultrasound it is -- it's going to look linear if it's flat, and it

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did.
Q. (By Ms. Liu) But you did not measure it as far as the thickness goes; is that correct?
A. I don't -- I don't remember whether I actually measured it in calibers.
Q. Did you measure the width, though, which is --
A. (Deponent nods head.)
Q. You did.
And what was the width on these ultrasounds that you -- what's the range of the width?
A. You know, I honestly don't recall what the range of the width was, but the findings were not concerning, alarming or something that's unexpected. So I would imagine it was in the range of about a centimeter.
Q. Did you record the width down?
A. No.
Q. So at this point you are not sure exactly what the width was. You are guessing that it was about a centimeter?
MR. SNELL: Misstates.
THE DEPONENT: No, I am not guessing. I -- I recall that it was about a centimeter. Because if it were significantly greater than that, well, that would

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then prompt a line of investigation to figure out why that would be, or if it was significantly less than that, again, we try to investigate why that would be.
So there was nothing that was surprising about the width of the mesh on that ultrasound image.
Q. (By Ms. Liu) And, Doctor, have you used the TVT original in the laser cut mesh?
A. I'm sorry. I don't quite follow the question.
Q. Okay. You mentioned that, currently, you are using mechanically cut TVT retropubic original mesh.
Have you ever used the laser cut mesh? Not in the EXACT, but in the retropubic original.
A. I don't remember.
Q. You mentioned in your report that, clinically, you found them to be the same. So that's why I'm wondering how you came -- you came up with that conclusion?
A. So I came to that conclusion as a result of doing the implantation. The -- my own personal bladder perforation rate and intraoperative complication rate, as well as intraoperative time, blood lost, all of these parameters that we look at in order to evaluate the flow of surgery, those were comparable.
And then, postoperatively, there was -- there

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was no difference in either efficacy or complication rates. And that is not unique to my practice, obviously. I rely on substantial body of literature also that corroborates my experience.

Q. Have you compared the laser cut mesh and the mechanically cut mesh in your own practice, as far as long-term clinical outcomes?

A. So at one year, which is what I can speak about most reliably, because everyone follows up to one year. There's -- there's not been a difference.

Q. Now, you mentioned you are not sure whether or not you have used the laser cut mesh in the TVT retropubic; is that correct?

A. So I have used the laser cut mesh with the -- with the TVT exact, which has a smaller trocar for certain. And I don't recall whether I have used the laser cut mesh with the original TVT introducer device.

Q. So as far as comparing the two, you can only compare your EXACT to the TVT original as far as laser cut or mechanically cut, correct?

MR. SNELL: Object. Misstates.

THE DEPONENT: So I think I can compare them based not only on my own experience, but, again, on the -- on the significant amount of literature that's been published on outcomes following the TVT with the

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use of mechanically and laser cut mesh.

And, again, I don't -- I don't know that the size of the trocar makes much of a difference, right? So the trocar doesn't stay in the patient afterwards. It's literally there for a few minutes and -- and it's then removed.

MS. LIU: Let's take a quick break.

(Recess taken.)

MS. LIU: Back on.

Q. (By Ms. Liu) Doctor, do you believe that mesh extrusion exposure and erosion is a risk of the TVT retropubic sling?

A. It's a known risk.

Q. But it is a risk, correct?

A. Yes.

Q. Infection is a risk; is that correct?

A. Infection is a risk of any surgical procedure. That is not unique to the implant.

Q. But it is a risk; is that correct?

A. It's a risk of surgery.

Q. Is it a risk that the implant would get infected?

MR. SNELL: Form.

THE DEPONENT: I -- I haven't seen that. And I am not sure what you mean by the implant getting

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infected. Like you mean just purulence around the implant? That's rare; although, I'm --

Q. (By Ms. Liu) Is it a risk, though?

MR. SNELL: Object. Form. Asked and answered.

THE DEPONENT: Infection is -- is a risk of surgery.

Q. (By Ms. Liu) Acute pain is a risk of the TVT?

A. Acute pain is a surgical risk. It's a risk of pelvic surgery and stress incontinence surgery, specifically.

Q. Is chronic pain a risk of the TVT?

A. Chronic pain is a risk of any pelvic surgery, including stress incontinence procedures.

Q. Including TVT?

A. TVT is a stress incontinence procedure that involves surgical placement of the TVT. So, yeah, chronic pain is a risk.

Q. Is voiding dysfunction a risk of the TVT?

A. Again, voiding dysfunction is a risk of any stress incontinence procedure.

Q. Including the TVT?

A. Including the TVT.

Q. What about pain with intercourse; is that a

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risk of the TVT?

A. Pain with intercourse is a risk of pelvic surgery and vaginal surgery. I don't think it's -- my opinion is that it's not directly linked to the TVT implant.

Q. What about neuromuscular problems; is that a risk of the TVT?

MR. SNELL: Object. Form.

THE DEPONENT: What do you mean by "neuromuscular problems"?

Q. (By Ms. Liu) Chronic pain in the pelvic or abdominal area because it passes through the musculature.

A. So we talked about chronic pain being a risk of any pelvic, abdominal or vaginal surgery.

Q. Recurrence of incontinence is a risk of the TVT implant; is that correct?

A. Recurrence of incontinence is a risk of any anti-incontinence procedure, including the TVT.

Q. Bleeding, including hemorrhaging or hematomas, are a risk of the TVT, correct?

A. They are a risk of pelvic, abdominal or vaginal surgery.

Q. Including the TVT?

A. Including the TVT, although lower with the

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TVT than other anti-incontinence procedures.
Q. Seroma is a risk of the TVT?
MR. SNELL: Object. Form.
THE DEPONENT: Seroma could be a risk in theory, but the risk of seroma formation with a minimally invasive procedure like a TVT would be much lower than with other anti-incontinence procedures that actually require an open abdominal approach.
Q. (By Ms. Liu) But it is still a risk, correct?
MR. SNELL: Object. Form.
THE DEPONENT: A small theoretical risk.
Q. (By Ms. Liu) Urge incontinence or frequency is a risk of TVT, correct?
A. It's a risk of any anti-incontinence procedure, including the TVT.
Q. Urinary retention, is that a risk of the TVT?
A. It's a risk of any pelvic surgery, not just anti-incontinence surgery. But, yeah, certainly patients who have anti-incontinence procedure are at risk of transient and longer-term urinary retention, and TVT is no exception.
Q. Adhesion formation, is that a risk of the TVT?
A. What do you mean by "adhesion formation"?

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Q. Well, what do you, as a doctor, define "adhesion formation" as?
A. Generally, when I'm referring to "adhesions," I'm talking about the obliteration of a real or potential space. And so we are not really talking about real or potential spaces except for the retropubic space. I imagine there may be some adhesion formation in the retropubic space.
Q. So that is a risk?
A. Of the -- of the TVT, as well as any other abdominal, pelvic or vaginal surgery. I believe lower with the TVT. Again, as I mentioned, you are not creating a real space within the retropubic space, you leave it as a potential space.
Q. And -- but it is -- adhesion formation in the retropubic space is a risk of the TVT, correct?
MR. SNELL: Object. Form.
THE DEPONENT: Yes.
Q. (By Ms. Liu) Atypical vaginal discharge, is that also a risk of the TVT?
A. What do you mean by "atypical"?
Q. Well, discoloration, foul odor.
A. So abnormal vaginal discharge has so many causes that I think it would be -- my opinion is that it would be impossible to say whether the TVT is

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directly related to it.
Q. But is it a risk?
MR. SNELL: Objection. Asked and answered.
THE DEPONENT: In the cases where there is mesh exposure in the vagina, it may be linked to abnormal vaginal discharge; although, there are certainly patients who have exposure who don't have abnormal vaginal discharge. But overwhelmingly, the cause of abnormal vaginal discharge is not the TVT, and it is certainly not -- a TVT that's not exposed is not the cause of abnormal vaginal discharge.
Q. (By Ms. Liu) So in cases where there is exposure, the TVT can be the cause of the abnormal vaginal discharge, correct?
A. Correct.
Q. Exposed mesh can cause pain to the patient's partner; is that correct?
A. During intercourse.
Q. Correct.
Is that a risk?
A. Yes.
Q. Okay. Is death a risk?
A. Death is the risk of life.
Q. Doctor, do you believe that all known risks of the TVT should be in the IFU?

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A. No, I don't believe that.
Q. Doctor, have you reviewed the IFU?
A. I have.
Q. Which ones?
A. I reviewed the 2015, as well as the 2011 IFU.
Q. And did you find the 2015 IFU to be sufficient?
A. The 2015, is that the one you are asking about?
Q. Yes.
A. I actually found both of them to be sufficient.
Q. Now, did you review any IFUs besides the 2015 and 2011?
A. About the TVT, specifically?
Q. About the TVT, specifically.
A. I don't think so.
Q. So you didn't review the 2000 IFU; is that correct?
A. I may -- I may have reviewed it.
MR. SNELL: You are allowed to look through your stuff, if it will help you to refresh your recollection.
MS. LIU: And I appreciate if Counsel would not coach the witness.

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MR. SNELL: I am not coaching her. It is -- she is allowed to do that.
MS. LIU: I'm not saying she is not.
MR. SNELL: For the record, the witness has brought boxes and boxes of materials -- of materials that she's reviewed. All I am stating is if she wishes, she can go and look at that before trying to answer a question about a specific document. There's nothing improper about that. And I didn't coach her as to whether she looked at it or not.
MS. LIU: You just said she brought boxes that she reviewed.
Q. (By Ms. Liu) Doctor --
MR. SNELL: Well, she's already testified to that.
Q. (By Ms. Liu) -- the boxes that you -- have you reviewed in detail every single document that you brought?
A. It depends on your definition of "in detail." But, yes, I have reviewed the documents that I have brought.
Q. In your 33-1/2 hours that you have billed?
A. Yes.
Q. So you reviewed all the documents that are there in the 33-1/2 hours and drafted your report,

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correct?
A. Well, some of these -- a large number of these documents are clinical trials that I have -- I was familiar with before I became an expert witness. It's just a part of the body of knowledge that I am expected to have as a pelvic reconstructive surgeon.
Q. And, Doctor, do you know the number of internal documents you have reviewed in preparing your report?
A. I didn't enumerate them.
Q. Would you say, you know, more than five? More than ten? Do you have a -- a good guestimate? A fair estimate?
A. If I had to estimate, I would say more than 50.
Q. So when you say "more than 50," are you saying 50 to 75?
Do you have a better range for that? What was the high end of your range?
A. I am not sure I can give you a range.
Q. Doctor, how did you receive these internal documents?
A. Some of them were on the thumb drives and some were with -- with duplication on -- on paper, hard copy.

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Q. Doctor, do you know how many documents have been produced in this litigation?
A. I didn't count off the documents, no.
Q. And, Doctor, do you know how defense counsel determined which documents to send to you?
A. So my understanding was that defense counsel sent the documents that were made available to the -- to the plaintiffs; that all of those were made available to me.
Q. Doctor, did you receive billions of pages of internal documents?
A. Billion of pages?
Q. Correct.
A. You know, I didn't count them up. Certainly there was electronic as well as hard copy, so I didn't -- I didn't count them.
MS. LIU: Doctor, I am going to mark the reliance lists that were provided by Ethicon for your report as Exhibit 4 and 5.
(Exhibit 4 was marked for identification by the court reporter and is attached hereto.)
(Exhibit 5 was marked for identification by the court reporter and is attached hereto.)
Q. (By Ms. Liu) Doctor, did you prepare the reliance list?

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A. I didn't prepare the reliance list.
Q. Do you know what -- strike that.
Do you know who prepared your reliance list?
A. Butler Snell prepared the reliance list.
Q. And, Doctor, did you know that Butler Snell submitted a supplemental reliance list this week?
A. I see that here.
Q. Did you prepare the supplemental reliance list?
A. I didn't prepare either of these lists.
Q. Do you know what the difference is between the two -- strike that question, actually.
Did you give Butler Snell additional documents to add to your reliance list?
A. Than what was previously outlined in my general report, I think there were a couple of articles about the incidence and prevalence of pelvic pain.
Q. And strike that -- move to strike.
My question was: Do you know -- did you -- did you give Butler Snell additional documents that were not in your original reliance list to add to your supplemental reliance list?
A. And by "documents," are you referring to citations?
Q. Anything. Any kind of document -- any

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additions that would be on your supplemental, did you provide them to Butler Snell to add?
A. So we discussed citations, but I didn't -- I'm not privy to company documents. So I certainly wouldn't be supplying them to Butler Snell, if that's what you are asking.
Q. Did you give them any additional articles? Is that --
A. Citation to articles.
Q. And, Doctor, did you review everything that is on your reliance list?
A. I did.
Q. And, Doctor, when did you review your reliance list?
A. So I reviewed my reliance list yesterday, as well as intermittently through the course of working on this.
Q. Doctor, do you know when your reliance list was created?
A. I don't know the exact day, no.
Q. Do you know when you received the reliance list?
A. So the supplemental reliance list, I received a copy of that yesterday morning. And the general reliance list, I don't recall the exact date of when I

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received it.
Q. Was it before or after you submitted your report?
A. I don't recall.
Q. Do you remember whether or not you reviewed design specifications for the TVT?
A. I did review design specifications for the TVT.
Q. Do you know how many?
A. I have read a number of articles about the design of the TVT.
Q. Articles?
A. And I have reviewed -- reviewed company documents about the design of the TVT as well.
Q. Do you remember whether or not you read specific design specifications?
MR. SNELL: Object. Asked and answered.
THE DEPONENT: I have read about specific design specifications.
Q. (By Ms. Liu) Doctor, did you review any corporate deposition testimony?
A. I did.
Q. Do you know who?
A. Oh, let's see here. I have reviewed the deposition testimony that's -- well, this isn't

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numbered, but under the materials list, you can see that there is Moore, Angelini, Axel Arnaud, Thomas Barbolt, and it just kind of goes on, as well as the expert witnesses.
Q. And, Doctor, you have reviewed every single one of these that is listed on your reliance list?
A. I am aware of them, yes.
Q. You are aware of them.
Did you read their deposition testimony?
A. I have read some of it. Probably not every single page.
Q. And, Doctor, did you review the expert reports of -- the general experts for the plaintiffs?
A. I have.
Q. Which ones?
A. Bruce Rosenzweig and Jerry Blaivas.
Q. Doctor, did you pull up the citations in their reports when you were reviewing them?
A. Do you mean did I read the entirety of every article that was cited in their report?
Q. Correct.
A. I didn't do that, no.
Q. Did you read any of them?
A. Yes.
Q. And why didn't you pull up every single

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citation that the plaintiffs' experts cited to?
A. Some of them I was familiar with. Some of them I looked at the abstract or just looked at the relevant results tables.
Q. And did you disagree with the plaintiffs' experts that you reviewed?
A. I disagreed with their opinions.
Q. Doctor, how many case-specific reports were you asked to produce in this litigation?
A. So I reviewed a total of four cases and produced case-specific reports for two of those.
Q. So you reviewed four cases.
In the two that you did not produce reports from, did you generate an opinion?
A. I did.
Q. And in the two cases that you did produce a report, you wrote up your opinion; is that correct?
A. Yes.
Q. In all four cases, did you conclude that the TVT was not the cause of the plaintiffs' symptoms?
MR. SNELL: Object. Form.
THE DEPONENT: So I concluded that the TVT implant did not directly cause the -- the symptoms or problems that -- that these patients had.
Q. (By Ms. Liu) And, Doctor, did you also read

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the depositions of the plaintiff experts?
A. I did.
Q. Which ones?
A. I thought we just did this. So --
Q. We talked about the expert reports. I'm now switching to the depositions --
A. Oh, the depositions. Okay. Gotcha.
So the same people, Bruce Rosenzweig and Jerry Blaivas.
Q. And, Doctor, did you read all of this material, including the deposition transcripts, within the 33-1/2 hours that you have billed?
A. Well, some of that was also done in the preparation of the case-specific reports, which are not reflected in that.
Q. And, Doctor, since you have produced this invoice, which is from November to January, how much time have you spent on the general TVT, including preparation for today?
A. So I haven't tallied it up because I haven't -- you know, I haven't submitted a bill, or anything like that.
Q. Do you have a best estimate?
A. Probably at least as much.
Q. So another 33-1/2 hours?

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A. If not more, yeah. Again, I haven't tallied it up.
Q. And in those 33-1/2 extra hours, what -- what did you do in preparation?
A. So I looked at company documents. I read the depositions of the plaintiffs' experts. I have reviewed medical records. I reviewed the depositions of -- of the plaintiffs themselves. I reviewed additional studies or re-reviewed the literature that I had relied upon.
Q. And, Doctor, you mentioned medical records and plaintiffs' depositions.
So you are talking about the case specifics now, correct?
A. So those, yeah, would be. Yes.
Q. So that extra 33-1/2 hours encompasses both the TVT general preparation, as well as the case-specific reports that you are relying on; is that correct?
MR. SNELL: Hold on. Object. Form. Misstates. She said "at least." You keep saying 33. She did not testify it was 33 hours.
THE DEPONENT: Right. So there's, I think -- I'm sorry. What was your question?
Q. (By Ms. Liu) Let's just -- you know, strike

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that. We will move on.
A. Okay.
Q. Doctor, earlier you mentioned the tissue ingrowth process, the four weeks for the initial acute phase; is that correct?
A. Yeah. I mean, it's not separated into phases, but the rapid incorporation of tissue and fibroblast ingrowth and neovascularization happens rapidly at the beginning.
Q. And then you mentioned that it continues on until approximately a year time; is that correct?
A. Yeah. And there's scar remodeling that happens even after a year, but at a much lower rate.
Q. Doctor, would you -- do you believe that chronic inflammation is a risk of the TVT?
A. I don't believe that, no.
Q. So this process where you have got continual tissue and growth and remodeling is not considered chronic inflammation to you?
A. No. So if you break up wound healing, it's -- it's broken up into four commonly recognized stages. Initially, after you create a wound, there's hemostasis, where the blood vessels contract in order to diminish blood loss.
Then there's an acute inflammatory phase

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where -- which is characterized by leaky blood vessels and the release of cytokines in order to call in, first, cells of the immune system to fight any infection that might be associated with a wound. And that's regardless of whether there's a foreign body or an implant, or whatnot.
Following that, you have got fibroblast ingrowth, neovascularization. And that's actually not the inflammatory part. That's -- that's the next phase of wound healing. And then there is scar remodeling where collagen types are switched from one type to another that is better organized.
Q. Doctor, have you examined mesh that's been removed under an electron microscope?
A. I haven't personally examined mesh that's been removed under an electron microscope, but I'm familiar with the studies that have examined mesh under the electron microscope.
Q. Have you -- strike that.
Doctor, so since you have not examined removed mesh under an electron microscope and the tissues that are incorporated into this mesh, you would not know whether or not there was chronic inflammation in the explanted mesh, would you?
MR. SNELL: Objection. Form. Lacks

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foundation as well.
THE DEPONENT: So when I explant mesh, there's no gross evidence of inflammation around the mesh. There's good tissue incorporation that's seen. You know, that's why it's sometimes difficult to remove mesh.
Q. (By Ms. Liu) But you have never actually examined mesh, like an explanted mesh piece, under electron microscope to see whether or not there's evidence of chronic inflammation; is that correct?
MR. SNELL: Objection. Asked and answered.
THE DEPONENT: I haven't, but I'm not -- I don't believe that an electron microscopy image would even be indicative of inflammation. I think inflammation is something that is better assessed with plain histology.
Q. (By Ms. Liu) And, Doctor, you are not a pathologist, are you?
A. I am not a pathologist; although, I've worked closely with pathologists.
Q. But you have never performed the work of a pathologist?
A. I'm not a pathologist.
Q. Doctor, we talked a little bit about the IFU earlier, and you had stated that you specifically

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remember reviewing the 2015 and the 2011 IFUs, correct?
A. Correct.
Q. Doctor, have you ever written an IFU?
A. I have not written an IFU.
Q. Have you ever given input to a medical device company on what needs to be in an IFU?
A. I have not.
Q. Would you consider yourself to be an expert in drafting IFUs?
A. I have used IFUs. I have been the end user, the intended audience of IFUs.
Q. But you have never drafted one, correct?
A. I have not drafted an IFU, not --
Q. Do you know -- sorry. Didn't mean to cut you off.
Do you know what the regulations are of what needs to be in an IFU?
A. So in preparation for this case, I -- I have reviewed some of the FDA regulations around IFUs.
Q. Do you know which regulations they were?
A. I don't remember the exact number. There -- there are lots of regulations, but they were specific for medical devices whose use would be limited to train physicians --
Q. Now --

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A. -- or clinicians.
Q. -- in these -- in these regulations that you reviewed, did you use them to draft an IFU?
A. I haven't drafted an IFU.
MS. LIU: I'm sorry. Can we take a quick break.
(Recess taken.)
MS. LIU: Back on.
Q. (By Ms. Liu) Doctor, in your report, you had some opinions on pore size; is that correct?
A. Yes, I discuss porosity and pore size in my report.
Q. And, Doctor, do you know what the pore size is in the TVT?
A. Yeah. It's 13- to 1400 microns.
Q. And do you know how that is measured?
A. So the length of the pore is measured, so fiber to fiber.
Q. And, Doctor, do you know what the shape of the pore is?
A. Yes. It's roughly a diamond-shaped, four-corner structure.
Q. So do you know from which -- which portion of the pore is measured, like what end to what end?
A. I don't know exactly which of the --

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you know, whether it's straight across or a diagonal, but I don't think that's clinically relevant.
Q. And, Doctor, the TVT is weaved, correct?
MR. SNELL: Object. Foundation.
THE DEPONENT: So the TVT is a monofilament macroporous knitted mesh.
Q. (By Ms. Liu) So it is knitted?
A. Right.
Q. And so, Doctor, you have got the pores, the one that you said is measured.
What about the little pieces or the little ones where you have got the -- the knitting, where there's much smaller; do you know what that size is?
MR. SNELL: Object. Form. Foundation as well.
THE DEPONENT: I'm sorry. The size of the knitting, what are you referring to?
Q. (By Ms. Liu) So if you look at a TVT, you will see the pore size that you just mentioned, the 13- to 1400 microns, correct?
A. Correct.
Q. So now between each pore, there's also knitting; is that correct?
A. No. The pores are -- are created by the intersection of the fibers, right? So there's -- there

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are places where the fibers touch and places where the fibers don't touch. The places where the fibers don't touch are the pores. Everything else is the fiber.
Q. Okay. And so where -- the areas where the fiber is touching, there's multiple fibers in -- in those corners; is that correct?
A. So -- I mean, technically, by definition, a corner is the lack of fiber. But, yes, fibers do come together for the knitting of the mesh.
Q. Okay. So where those fibers come together, do you know what the pore size is in between each of those fibers?
MR. SNELL: Object. Form. Asked and answered. It lacks foundation.
THE DEPONENT: So where the fibers come together, they are actually touching. So there's no space between them. And then the fibers gradually widen to a maximum of, you know, probably roughly 1400 microns, if we assume that that was measured on a diagonal. More than that if it was measured straight across.
Q. (By Ms. Liu) And, Doctor, do you know the definition of "effective pore size"?
MR. SNELL: Objection.
THE DEPONENT: There's not a standard

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definition of "effective pore size." But according to Amid classification, TVT polypropylene mesh is a Type 1 monofilament macroporous mesh, as defined by pore size greater than 75 microns. So the TVT pore size is roughly 20 full path.
Q. (By Ms. Liu) And, Doctor, what I mean by "effective pore size" is, you know, after the mesh is implanted, do you know what -- how the pore size change after the measure is implanted?
MR. SNELL: Object. Foundation.
THE DEPONENT: So I -- I don't have any reason to believe that the pore size changes after the mesh is implanted.
Q. (By Ms. Liu) Do you know what the forces of the pelvic floor or the -- the area under the urethra are after the mesh is implanted -- what the forces are on top of the mesh?
MR. SNELL: Object. Form. Compound.
THE DEPONENT: So there have been studies that look at the forces on the pelvic floor that are generated as a result of a variety of activities, you know, including carrying laundry or constant -- you know, Valsalva with constipation.
Q. (By Ms. Liu) And do you know what that does to the pore size?

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MR. SNELL: Lacks foundation.
THE DEPONENT: It doesn't effectively change the pore size within the physiologic range.
Q. (By Ms. Liu) So you don't believe that the movement or the forces on the pelvic floor stretch the mesh after implantation?
A. So the mesh may elongate slightly after implantation. And I think there are -- or I know there are published studies to quantify that. But with physiologic forces, that is an insubstantial elongation, so the effective pore size remains roughly the same.
Q. And that is your belief; is that correct?
A. That's my opinion.
Q. It is your opinion. So it is your opinion that the pore size remains approximately the same?
A. Yes.
Q. Okay. Doctor, do you believe that the mesh shrinks after implantation?
A. I don't believe that the mesh shrinks after implantation, no.
Q. Is there evidence in the literature that the mesh shrinks?
A. There's -- there's suggestion to support mesh surface area remaining the same. There are conjectures

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about mesh shrinkage as well. But I think that based on what I have seen, both in the literature about these explanted samples, as well as in my own clinical practice, is scar tissue remodeling and reaction of the native tissue around the mesh -- there's not been anything to suggest that the mesh itself shrinks.
Q. So in reviewing the documents, the internal documents, did you see anywhere where Ethicon internally stated that the mesh can shrink 30 percent?
MR. SNELL: Object. Lacks foundation as to Ethicon.
THE DEPONENT: So I have -- I have reviewed company documents, and I have reviewed a variety of tests that were performed in vitro in the lab on the mesh, including tensiometry testing and pull-out strength. But those tests, in my opinion, have less bearing to me than the clinical data in my own clinical experience, and the safety and efficacy profile of the TVT slings suggest that the mesh does not shrink or contract.
And that's actually borne out by several studies that look specifically at -- at the mesh, as well as tissue mobility around the mesh; for example, urethral mobility.
Q. (By Ms. Liu) And, Doctor, for the studies

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that you suggest, that the mesh shrinks, did you not consider that?
A. I did consider them. Yeah, I considered --
Q. And what weight --
A. -- all the relevant evidence.
Q. What weight did you put on each of those types of articles or studies?
A. Are you asking me to quantify something? I am not sure what you are asking me.
Q. Well, you have said that you considered all of them. But clearly, you are considering the studies that you believe and that support your opinion.
So did you give the -- the studies that state that the mesh does shrink less weight than the ones that support your opinion?
A. Well, I generally don't base weighting studies, as you put it, on the outcomes of the studies. I base it on the methodology, the study design and the level of evidence that the studies fall under, not the result of the studies.
Q. And did you give any weight to the internal documents that suggests that the mesh shrinks?
MR. SNELL: Object. Lacks foundation.
Go ahead.
THE DEPONENT: Again, I considered internal

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documents. I don't think that the -- my conclusion from the internal documents wasn't that there was definitive evidence of mesh shrinkage. And, generally, I give more weight to higher-level evidence, peer-reviewed level-1 evidence preferably as compared to internal company documents about the -- the pre-clinical design of the TVT.
Q. (By Ms. Liu) Now, Doctor, are you aware that some doctors will report to a manufacturer when they have complications?
A. I'm aware of that, yes.
Q. Have you ever done so?
A. Specific to the TVT sling?
Q. Anything.
A. I have given feedback to manufacturing representatives, but I haven't written a formal complaint, no.
Q. Now, you would expect that the manufacturer, when they do receive complaints, would make note of it, correct?
A. Yes.
Q. And you would expect them to analyze the data that they receive, correct?
A. It depends on what you mean by "analyze the data." Oftentimes, there's not data that they receive,

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right? I mean, I -- oftentimes, these complaints come in the form of unquantified expressions of a single user's single experience. So I am not sure that you can make a case for analyzing something like that.
Q. So if a manufacturer receives, you know, hundreds of complaints about the same thing, you would expect them to keep a log of this, correct?
A. Yeah. I would want them to be aware of the complaints that they are receiving.
Q. And would you agree that the manufacturer would have the best knowledge of what's going on -- going on in the field as far as complications or complaints go about their product?
MR. SNELL: Objection. Form. Lacks foundation as well.
THE DEPONENT: I don't -- I don't necessarily agree with that, no. I think that the -- the end users in the academic community performing -- you know, let's go back to the case of the TVT, for example. Pelvic reconstructive surgeons would probably have the best knowledge of the issues surrounding a specific procedure.
Q. (By Ms. Liu) So you don't believe that the manufacturers, say, of the TVT Ethicon would be the best source of information dealing with complaints or

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complications about their product; is that correct?
MR. SNELL: Objection. Asked and answered.
THE DEPONENT: I -- in this specific case, we are so far into the litigation that I imagine Ethicon has a pretty good sense of what the complaints are and has painstakingly reviewed them. But if we are talking in general about a surgery procedure that involves -- you know, whether an implant or a device or whatnot, no. I would not expect that the manufacturer have their finger on the pulse of all of the complications or latest developments. I think that is for the practicing community that actually utilizes that.
Q. (By Ms. Liu) And do you believe that the manufacturer who is selling the product should be keeping up with all the -- all the complications about their product?
A. I don't think -- I think they shouldn't be ignoring those complications, certainly.
Q. Doctor, do you believe that the TVT mesh has a potential to degrade?
A. I don't believe that, no.
Q. Doctor, have -- you stated -- strike that.
Doctor, you stated earlier that you have not looked at any explanted mesh under electron microscope; is that correct?

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A. I haven't personally looked at explanted mesh under an electron microscope.
Q. And so you haven't seen whether or not, with your own eyes, that the TVT mesh can degrade; is that correct?
MR. SNELL: Objection. Form. Misstates.
THE DEPONENT: So I have -- I haven't seen degradation with my own eyes, and I don't believe that the mesh degrades. But I have seen studies that included electron microscopy images of surface irregularities and roughness that the authors concluded may be indicative of mesh degradation.
Q. (By Ms. Liu) Okay.
A. Those studies were later refuted by other studies that -- that process the mesh in more complete and thorough ways, showing that there was actually no residual roughness or -- or surface cracking and that this was biologic in origin.
Q. Doctor, have you seen an article by Dr. Talley?
A. Show me the article that you are referring to.
Q. I only have the abstracts. I don't have the actual article with me. So I can show you the article, but --

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A. Could I take a look at the abstract that you are referring to?
Q. Sure.
Doctor, I just handed you an article. I have not marked it as an exhibit. That's my only copy.
A. I'll give it back to you, don't worry.
Q. I just want to see if you have ever seen it before.
A. So I am familiar with some of the authors.
I will let you go ahead and ask your question.
Q. Doctor, in your searches you mentioned that you did PubMed searches and the MEDLINE searches?
A. Uh-huh.
Q. Did you review the article by Dr. Talley?
A. I don't remember whether I reviewed that exact article. I certainly reviewed a number of articles about electron microscopy and processing of the mesh in order to -- to determine whether or not it degrades.
Q. And it is still your opinion that it does not degrade, correct?
A. Yeah, my opinion is that the mesh does not degrade. And that's based on -- not only on the -- the more translational and -- and benchwork studies, but it

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is also corroborated by all of the clinical data that shows sustained efficacy in the long term in terms of stress incontinence cure for women who have had the TVT implant.
Q. And, Doctor, your experience is clinical experience, correct?
A. Well, my experience is my own clinical experience, but it is also the -- the added experience, so to speak. We are all privileged to have the added experience of the entire academic community that publishes studies and also that then creates meta-analyses to pool the data.
Q. And, Doctor, have you designed any mesh products before?
A. I haven't designed mesh products, no.
Q. Do you know what goes into the design of a mesh product?
A. Well, it depends on what you mean by "design," but I have a rough understanding of what went into the design of the TVT, for example, based on the articles that I reviewed by Petrus and by Olmsted.
Q. And, Doctor, you mentioned Olmsted.
Are you aware that Olmsted was compensated based on positive results?
MR. SNELL: Object. Lacks foundation. Also

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misstates the evidence.
THE DEPONENT: So I am aware that Dr. Olmsted was compensated. I would expect that he would be compensated for his work and invention.
Q. (By Ms. Liu) And, Doctor, were you aware that Dr. Olmsted was -- was paid based on a contingency that he had positive results?
MR. SNELL: Same objection. Lacks foundation. Misstates the evidence.
THE DEPONENT: That he had positive results as a result of the TVT?
Q. (By Ms. Liu) Correct.
A. Yeah, I was aware of that.
Q. And does that -- your awareness of that, does that influence you as far as whether or not you -- how much weight you give his study?
A. Well, it's not just one single study and I -- if his study and his results were an outlier and there was some kind of compensation scheme to reward him for reporting specific results, then would give me pause with a study that that has results that are not congruent with the rest of the scientific community.
But his results are actually pretty much in line with randomized clinical trials and meta-analyses of these in terms of both the safety and the efficacy

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profile of the TVT sling.
Q. And, Doctor, as far as literature goes, do you give weight to -- strike that.
Doctor, as far as the literature goes, if you see that there's a disclosure of a conflict of interest, do you take that into account as to how much weight you give the study?
A. So I think conflict of interests must -- conflicts of interest must be considered. But how much weight I give a study ultimately depends on the study methodology, the number of patients, the study design, the measurement tools that were used.
So much more goes into evaluating a study than just who wrote it or -- but, yeah, that's why we have conflict of interest disclosures -- right? -- to make more transparent whether there may be some kind of financial motivation.
Q. And you do believe that every study -- if there is a conflict of interest, it should be disclosed, correct?
MR. SNELL: Object. Form.
THE DEPONENT: I believe that at least in my professional lifetime, medical journals have required conflict of interest disclosure forms from all authors that submit papers for publication.

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Q. (By Ms. Liu) Doctor, do you belong to any organizations -- any medical organizations?
A. The American Urogynecologic Society, the Society of Gynecologic Surgeons, ACOG.
Q. Doctor, I am going to hand you what I have marked as Exhibit 6, and that is your CV?
A. My CV.
(Exhibit 6 was marked for identification by the court reporter and is attached hereto.)
Q. (By Ms. Liu) Doctor, is that your current CV?
A. This is the -- the updated copy.
Q. Okay. And, Doctor, I am sure you are aware that there have been society papers on mid-urethral slings, correct?
A. Are you referring to position statements?
Q. Position statements.
A. Uh-huh.
Q. And in those position statements, do you believe that conflicts of interest should be disclosed?
A. Yes.
Q. And if they aren't disclosed, is that a problem?
MR. SNELL: Object. Form.
THE DEPONENT: It's not necessarily a

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problem, but it could be basis for a problem. So that's why, generally, conflicts of interest are -- the conflicts of interest are disclosed.
Q. (By Ms. Liu) Okay. And, Doctor, you mentioned earlier that -- I know I'm skipping around, but, you know, when you mention something, I go down that path. I am not very good at following my own outline, so...
A. No problem.
Q. Doctor, you mentioned, you know, the different types of -- you are using clinical trials, you are using literature a lot to base your -- your opinions.
A. Uh-huh.
Q. Doctor, do you believe that the majority of the literature out there, the primary outcome is on efficacy of the mid-urethral sling?
MR. SNELL: Object. Form.
THE DEPONENT: So there's a variety of studies, but efficacy and cure of stress incontinence, whether that's by single measure or compound measures, is often the primary outcome.
Q. (By Ms. Liu) And, Doctor, when certain studies look at complications --
A. Uh-huh.

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Q. -- if they are looking for a specific complication, like a -- an intraoperative complication, that's what that primary outcome -- not necessarily -- strike that. Let me -- that was a terrible question.
Doctor, when a study looks at a complication, it doesn't look at all complications, does it?
MR. SNELL: Object. Form. Incomplete hypothetical.
THE DEPONENT: So it depends on study design, but, generally, studies will report on all of the complications encountered within their sample.
Q. (By Ms. Liu) And, Doctor, are you familiar that many studies have questionnaires that they provide to the patients?
A. The -- validated questionnaires, yes, that are part of the subjective outcome measures.
Q. And if these questionnaires have specific questions like voiding dysfunction or -- let's just start with that.
If -- if it is talking about voiding dysfunction, it's not necessarily collecting information, say, on dyspareunia or chronic pain, is it?
MR. SNELL: Object. Form.
THE DEPONENT: So it depends on the

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questionnaire. And, again, that's something that you would look at when you are evaluating the study based on the methods, right? So there are sexual function questionnaires that are specific to dyspareunia, libido, et cetera.

And so if -- if you are evaluating a study based on -- to see, well, what are the results in regard to sexual function, yeah, you are going to go to the methods and make sure that they used a sexual function specific questionnaire.

Q. (By Ms. Liu) And I guess my question is: Each study has a different -- has different data points, correct?

A. Correct.

Q. And so whatever the data points are that are collected in those studies is what is being reported, correct?

A. So in those individuals studies, yes. And then with the wealth of studies that are available about mid-urethral slings, in general, and with the TVT specifically, we can then also pool all of these studies and look at combined data points in the scope of meta-analyses.

Q. And I believe you mentioned two such meta-analyses.

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One was the Schimph study and one was the Cochrane review; is that correct?

MR. SNELL: Object to form.

THE DEPONENT: Those are at least two of the meta-analyses and systematic reviews that I mentioned in my report, yes.

Q. (By Ms. Liu) And in both of those studies, the authors specifically state that the data that they used to collect was only moderate-level evidence; is that correct?

MR. SNELL: Objection. Lack of foundation.

THE DEPONENT: So the data that was used in those studies was the highest-level evidence that is available at the time about the TVT. And so some of that was case series which is -- which is not level-1 evidence, but some of that was randomized clinical and surgical trials which is level-1 evidence.

Q. (By Ms. Liu) But both studies did have the disclosure that it was a moderate level of evidence that they used, correct?

A. Yeah, I think --

MR. SNELL: Hold on. Same objection as before.

THE DEPONENT: The authors are very transparent about which studies they included and what

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level of evidence those studies fell under.

Q. (By Ms. Liu) So as far as the meta-analyses, if they are meta-analyses of the highest level of evidence, then that particular evidence is also somewhat suspect; is that correct?

MR. SNELL: Objection. Lacks foundation.

THE DEPONENT: I guess I would disagree with the word "suspect." I don't think it makes them suspect. You have to review the evidence in -- in the context in which it was gathered and analyze it within that context to recognize its limitations, but it doesn't make it suspect.

Oftentimes it can be -- you know, what you might be referring to is that it can be incomplete. For example, there's some studies that may not have included a specific validated questionnaire. And that's why we have large multi-centered networks in order to ensure that we produce high-level data. And those networks have done studies on TVT.

Q. (By Ms. Liu) And, Doctor, you don't know how many studies include long-term chronic pain as a data point, do you?

A. Are you asking specifically about the TVT --

Q. Yes.

A. -- how many studies about the TVT report

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long-term chronic pain?

Q. Correct.

A. So there are studies that attest to the long-term chronic pain outcomes that query patients about dyspareunia and chronic pain, but chronic pain is -- is -- assessment of that is also somewhat difficult because there's oftentimes not a linear causality with chronic pain.

And chronic pain is such a common preexisting condition that is associated with pelvic floor disorders, in general, of which stress urinary incontinence is one that it's -- you know, there -- there are challenges in -- in attributing -- a specific -- pelvic pain to a specific cause.

Q. Now, Doctor, in many of those studies -- in most of these studies, would you agree that the studies track pain just in the postoperative period?

MR. SNELL: Object. Foundation.

Are we talking about TVT studies?

MS. LIU: TVT, yes.

THE DEPONENT: So let me just rephrase your question back to you.

Are you asking me whether studies report on postoperative pain after TVT?

Q. (By Ms. Liu) No. Sorry.

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My -- my question is: Most of these studies that you have cited that -- that track pain, is it mostly in the postoperative period, say, up to the, you know, six-month point?

A. Well, so it depends on the study, right? Some studies report their results at a year, some at two years, some at five years.

Q. So how many long-term studies, say, that's over five years is chronic pain a primary data point?

MR. SNELL: Object. Form.

THE DEPONENT: Do you mean a primary endpoint of the study --

Q. (By Ms. Liu) Sure.

A. -- or a primary objective?

It's reported in a number of studies, but I don't think it's the primary objective.

Q. What about long-term chronic dyspareunia related to TVT; is that a primary endpoint in the studies that you have cited to?

MR. SNELL: Object. Lacks foundation.

THE DEPONENT: So it would be difficult to do -- to use that as a primary outcome with TVT because it's not -- dyspareunia is not a result of the TVT. So I don't think there would be investigators to -- to undertake those studies; however, there are studies

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that look specifically at dyspareunia after stress incontinence surgery, not the TVT, and after pelvic reconstructive surgery, in general.

Q. (By Ms. Liu) And, Doctor, I know that I skipped around a little bit. I want to circle back around to your experience.

Your experience, in generating your report, has been clinical experience, correct?

MR. SNELL: Object. Misstates.

THE DEPONENT: So, again, my experience is a combination of my own clinical experience, the clinical experience of my colleagues, my training, my review of the literature; and specific to the generation of the report, also my review of company documents.

Q. (By Ms. Liu) And, Doctor, you stated before that you have not designed a medical device.

Have you designed any type of polymer before?

A. I have not designed a polymer.

Q. You wouldn't purport yourself to be a polymer expert, would you?

MR. SNELL: Objection.

THE DEPONENT: I believe that I am an expert in the polypropylene polymer based on my clinical use of it, based on my review of the literature surrounding its design and applications.

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Q. (By Ms. Liu) Are you a materials engineer?

A. I don't have that degree, no.

Q. Have you designed any materials before?

A. I haven't personally designed materials.

Q. Have you provided any input to a medical device company on how to design a sling, for example?

A. Informally, I have given feedback about the -- the clinical applications of mesh.

Q. And have you given any opinions to a medical device company as to the weight of the mesh -- of what the mesh should be?

A. I haven't personally done that, no.

Q. Have you given a medical device company what you believe the pore size -- the optimum pore size of the mesh should be?

A. So, again, not personally, because those questions were actually answered before I was mid-career, right? I'm fortunate to practice in a time where those questions have been answered.

Q. So -- but to answer my question, you have never given, then, any opinion as to how the TVT or any type of sling should be designed, correct?

A. Correct.

MR. SNELL: Object to form.

MS. LIU: Off the record.

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(Recess taken.)

MS. LIU: Back on.

Q. (By Ms. Liu) Do you know what Ethicon's internal standard operating procedures are related to design?

MR. SNELL: Object. Form. Overbroad. Lacks foundation as to the device.

THE DEPONENT: I -- I -- can you repeat the question. I'm sorry.

Q. (By Ms. Liu) Sure.

Have you -- first off, have you reviewed any internal documents about Ethicon's standard operating procedures related to the design of the TVT mesh?

A. So I have reviewed internal documents from Ethicon related to the TVT mesh, yes.

Q. And these are standard operating procedures on how it is supposed to be designed, correct?

A. Again, you know, I -- I am not sure whether they are standard operating procedures. They are -- they are documents and internal company communications around the design of the TVT sling.

Q. Would you agree that Ethicon did not design the TVT mesh to rope?

A. I would agree that the sling is not designed to rope, nor does it rope.

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Q. Move to strike the "nor does it rope." That was not my question.
My question was: Was it designed to rope?
A. It wasn't designed to rope.
Q. Was it designed to curl?
MR. SNELL: I am going to note my objection to the motion to strike. I think it was responsive. And certainly Judge Eifert, in this litigation, has stated that a witness may give a responsive answer in furtherance or the basis for the answer. So I think her answer was proper.
THE DEPONENT: Curling, is that what you are asking about now?
Yeah, the mesh was not designed to curl and it doesn't curl.
MS. LIU: Move to strike "and it doesn't curl."
Q. (By Ms. Liu) My question is just: Is it designed to curl?
MR. SNELL: So same counter.
Go ahead. Asked and answered now.
THE DEPONENT: It's designed to -- to lay flat under the urethra.
Q. (By Ms. Liu) Is Ethicon -- is the TVT designed to fray?

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A. I don't -- I don't believe that the TVT is designed to fray, nor is there fraying under physiologic implantation conditions.
Q. And, Doctor, you already testified that you haven't seen the mesh and explanted mesh under electron microscope, correct?
MR. SNELL: Objection. Asked and answered.
THE DEPONENT: Under electron microscopy, no.
Q. (By Ms. Liu) Doctor, is the TVT designed to lose particles?
A. So I think we covered this earlier in my testimony. But there are blue particles that are released from the mechanically cut TVT mesh when that mesh is cut with scissors, for example.
Q. And, Doctor, is the TVT mesh designed to easily deform?
A. So I think that -- to answer that, I would have to say that the TVT mesh is designed to be not so stiff as not to deform under super physiological forces. But when it is under physiological forces, the TVT does not deform.
Q. You did mention that it does elongate, correct?
A. It can elongate.
Q. And have you measured how much it elongates

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after implantation?
MR. SNELL: Objection. Foundation. Assumes facts not in evidence.
THE DEPONENT: It does not elongate after implantation. The elongation that I was referring to is in vitro elongation with benchwork studies using a tensiometer. And so those studies were then used to extrapolate an explanation for the excellent clinic performance of the TVT relative to some of the other meshes where -- so I'm referring specifically to Pam Moallis' study.
And in the discussion, they make a point about the low incidence of voiding dysfunction, urinary retention or mesh extrusion, or erosion with the TVT possibly because it's less -- it's a less stiff mesh. But their study isn't clinically based. It actually compared a number of different sling types in -- in the lab.
Q. (By Ms. Liu) Doctor, has anyone tested whether or not the mesh elongates after implantation?
A. So I believe there's small case theories on ultrasound -- with ultrasound studies to look at the length of TVT that have found no change in the length of the sling.
Q. Now, Doctor, the sling is cut, correct?

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MR. SNELL: Object to form.
Q. (By Ms. Liu) At the suprapubic puncture, they are cut, correct?
A. Yeah, the mesh is trimmed just below the skin line.
Q. So in these ultrasounds that you are talking about, how can someone know exactly how much mesh was implanted?
A. Well, so -- if you are asking about study design, we know the entire length of the TVT sling prior to implantation, right? So if I were trying to figure out the amount of the length of mesh that remains, then it would be a several-touch-point exercise where I would measure the amount of mesh that's given back to the surgical scrub tech and -- and from the total starting length subtract whatever was given back. And then if I were doing an ultrasound study, I would measure that length and compare it to that number at the time of implantation.
Q. In these small case series that you are talking about, do you know whether or not everything was measured prior to the ultrasound?
A. So I was actually referring not to a published case series, but to a study that Elizabeth Mueller was carrying out when I was a fellow.

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And I don't believe she published that data. That just never met the recruitment -- the number needed to recruit.
Q. So this is just a small number of people and not a peer-reviewed study that you are referring to?
A. Correct.
Q. And, Doctor, we talked a little bit about shrinkage earlier.
Do you, in your mind, have a difference between the word "shrinkage" and "contraction"?
A. So these words are used -- they are not actually medical terms. They are just -- they are used in a variety of settings. So maybe you could tell me what you mean by them and I will let you know if I agree.
Does that sound fair?
Q. Well, Doctor, do you believe that the mesh contracts after implantation?
MR. SNELL: Objection. Asked and answered.
THE DEPONENT: I don't believe that the mesh contracts, no.
Q. (By Ms. Liu) Okay. Doctor, after you implant a TVT, is it supposed to be palpable?
A. Through the vagina?
Q. Through the vagina, yes.

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A. By whom?
Q. By the physician. Like when you examine a patient with -- who has a TVT sling, is it supposed to be palpable?
A. And by "palpable," do you mean unextruded mesh that is completely covered by the vaginal skin, is that palpable?
That's dependent on a lot of patient characteristics. So in a well-estrogenized rugae vagina, the sling is very rarely, if ever, palpable. There are cases in which vaginas are atrophic or stenotic, lack the normal rugation, the skin is thin, and then an experienced examiner that's specifically looking for an implant may be able to palpate it through the vaginal mucosa.
Q. And when it's palpated, it's not supposed to feel like a band, is it?
MR. SNELL: Object. Form.
THE DEPONENT: I don't think there's really any consensus on what it should feel like.
Q. (By Ms. Liu) Should it feel like it's contracted?
A. I don't -- I don't know what -- what a contracted band would feel like, you know.
Q. Doctor, if you feel the mesh, should it feel

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hard or should it feel incorporated into the tissues?
MR. SNELL: Object. Form.
THE DEPONENT: So, again, there's not consensus on how the mesh should feel. Most of the time, you cannot feel the mesh. There are times when you can feel the mesh, and there's really no clinical significance to it. The patient is not aware. Her partner is not aware. So I don't think anyone really can -- I know that no one can say what a sling should or shouldn't feel like, if it's not extruded.
Q. (By Ms. Liu) Doctor, have you seen an article by a Dr. Sue Ross?
A. I would have to see the article. I don't memorize the authors.
Q. It was an article that was -- that talks about banding and palpable mesh.
Do you recall reading an article about banding --
A. Banding and palpable mesh?
Q. Yes.
MR. SNELL: Hold on. Objection as to foundation.
Is this a TVT study or just some random study you're talking about?
MS. LIU: It's a TVT versus TVT study.

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MR. SNELL: I'm going to object, actually, to foundation because that's not what that study is about. That misstates the evidence, then.
Q. (By Ms. Liu) Doctor, do you recall that study?
A. So I -- I don't -- I may have looked at it, but I -- without having the study in front of me, I can't comment to any of the data in that study.
Q. So if you had read the study, would it have made an impression on you if you read that over 22 percent of the patients in that study with a TVT retropubic sling -- their sling is palpable?
MR. SNELL: I'm going to object again. That misstates the evidence. Counsel very well knows that was not a TVT study.
THE DEPONENT: So your question is, would I be impressed by this.
I think there are a number of other factors I would have to consider, such as the total number of patients who were in the study, as well as whether this was just a random isolated finding noted by the clinician on physical exam or if it was correlated with any clinical outcomes, patient complaints, et cetera.
Q. (By Ms. Liu) Doctor, have you considered --
MR. SNELL: Are you done with the Ross study?

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MS. LIU: Yes.
MR. SNELL: Just note defense counsel's objection. Lacks foundation. Misstates the evidence. That study was a study concerning Boston Scientific Advantage versus the Obtryx. It did not involve the TVT retropubic device. Thank you.
Q. (By Ms. Liu) Doctor, have you considered using other types of mesh besides TVT in stress incontinence?
A. I have considered it, yes.
Q. And have you performed pelvic organ prolapse surgery?
A. Yeah. I do that as a routine part of my practice.
Q. With mesh?
A. The sacrocolpopexy is one of my go-to operations for advanced apical prolapse in healthy younger women.
Q. And what kind of mesh do you use for the sacrocolpopexy?
A. So I have used a variety of meshes, but it is macroporous, polypropylene monofilament mesh.
Q. Do you use the Gynemesh?
A. I have used the Gynemesh.
Q. What do you do use currently?

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A. Currently, I'm using the Restorelle mesh.
Q. And, Doctor, have you compared the Restorelle mesh with the TVT mesh?
And when I say "compare," I mean visually, touch?
A. Yeah, I have handled both of these meshes.
Q. And, Doctor, have you considered whether or not the Restorelle mesh -- sorry, strike that.
Doctor, in your comparison of the Restorelle versus the TVT mesh, do you notice that the Restorelle mesh is larger pore?
A. I do notice that.
Q. Do you notice that it's lighter weight?
A. It has less material per surface area.
Q. And, Doctor, do you -- have you ever tested the difference between the Restorelle mesh versus the TVT mesh, as far as sling material goes?
MR. SNELL: Object to form.
THE DEPONENT: I wouldn't want to test it. I mean, I -- when I perform surgery on a woman, she is taking on the risk, right? It's not me that is taking on the risk. So when I'm counseling her, I prefer very much to have the highest level of evidence available in order to counsel her about the risks and the expected outcomes of a procedure.

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And so that's one of the primary reasons for why I feel so comfortable with the TVT. There is a wide body of literature to support use of the TVT specifically with regard to efficacy, safety, durability. There's no data to rely on with regard to Restorelle mesh in a sling, and I -- I suppose I could just go rogue and fashion my own sling made out of Restorelle mesh, but I don't think that would be fair to my patients.
Q. (By Ms. Liu) Doctor, have you considered whether or not the Restorelle mesh or a lighter-weight mesh would be safer than the TVT?
MR. SNELL: Sorry. Go ahead. Object to form.
THE DEPONENT: Yeah, I considered it. And I have arrived at the conclusion that the TVT is currently the safest operation for stress urinary incontinence.
Q. (By Ms. Liu) And do you know why the Ethicon would call the TVT Prolene mesh "old construction mesh"?
MR. SNELL: Object. Foundation as to Ethicon.
THE DEPONENT: So I have seen company documents that refer to it as such, and I think that

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that is a semantic term that reflects the temporality of mesh development.
Q. (By Ms. Liu) Is that your opinion based on asking them the question as to why they call it that?
A. It is my opinion based on review of the documents. So the -- the older mesh was the mesh that was developed first.
Q. And do you know whether or not Ethicon took on trying to develop a better mesh?
A. Well, they -- they went on to develop additional meshes for a variety of applications, as I would expect them to do.
Q. Do you know whether or not they tried to develop a better mesh for stress urinary incontinence?
MR. SNELL: Objection. Form.
THE DEPONENT: So they attempted to develop a lighter-weight mesh with an absorbable component. Then they tested this mesh and it didn't perform well in tests.
Q. (By Ms. Liu) Do you know what it was called?
A. It was called the Ultrapro.
Q. Have you heard of the term "TOPA," T-O-P-A?
A. I may have. I don't remember.
Q. Do you remember whether or not you reviewed any testimony related to TOPA?

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A. I may have. I just -- I don't recall.
Q. Have you ever reviewed any documents relating to Scion?
A. Yes. That -- that definitively rings a bell. I would have to see those documents to know exactly what they were about. But I believe that was a project, yes.
Q. Do you remember what that project was about?
A. I would have to look at it again to tell you exactly.
Q. Did you read -- did you talk to any of the engineers about this project?
A. I didn't personally talk to the engineers, no.
Q. And do you know what the pore size or weight or material that was used in these projects?
A. So what can I tell you is that Ethicon has tried a variety of meshes, not just in the stress incontinence application, but also in the pelvic organ prolapse application, and Ultrapro was one of these meshes. And the absorbable component -- the absorbable fibers of this mesh did not perform well in testing. So it wasn't clinically released.
Q. And that was your understanding; is that correct?

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A. That was my understanding of what I reviewed.
Q. And, Doctor, we talked a little about inflammatory response or foreign body reaction.
Do you remember that?
A. We talked about inflammation, yes.
Q. And is that the same to you as "foreign body reaction"?
A. No, not necessarily. That's why we have the two separate terms.
Q. So can you describe what "foreign body reaction" is?
A. Yeah. Foreign body reaction is either gross or histologic, microscopic findings that are consistent with an implant of an exogenous product. So that can be either a synthetic product or a biologic graft.
Q. And would pore size affect how much foreign body reaction occurs?
A. So the -- the foreign body reaction is modulated by pore size, but there's not a scale -- a quantitative scale of foreign body reaction. So when you ask how much, that's difficult for me to answer.
Q. What about the -- let's just use it as a scale, not necessarily a definitive number.
So if the pore size was larger, it would be a less foreign body reaction.

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Would you agree with that?
MR. SNELL: Lacks foundation.
THE DEPONENT: So it's much more than just pore size. Pore size is one of the factors that we consider in a foreign body reaction.
Q. (By Ms. Liu) Would you consider density of the mesh?
A. You would consider the -- the origin of the material itself, the density, the pore size, the antigenicity. You would consider a lot of factors.
Q. You would consider the volume of the mesh?
A. So, yeah, you would consider the shape and the volume of the mesh.
Q. You mentioned origin.
Do you know where the polypropylene comes from?
A. It's manufactured. It's synthetic.
Q. Do you know what -- sorry. Strike that.
Do you know what additives are put in with the polypropylene mesh when they design the TVT?
A. I couldn't give you a complete list of the additives that are put into the TVT. But I -- I know about the downstream clinical effects as a result of the TVT that have convinced me that it's -- it's safe for use.

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Q. But you don't know what the additives are; is that correct?
A. I don't know a list of all the additives, yeah.
Q. Do you know why additives are even put into the mesh?
A. Well, I know there is a plastic sheath over the mesh. If you are referring to the -- the chemicals and solutions that are used in the manufacture of the polypropylene, polymers themselves, no, I don't know that.
Q. And you don't know the reason why they are added into the fibers, correct?
A. So I don't know what they are. As a result, I wouldn't know why they are added.
Q. And, Doctor, do you believe that the TVT polypropylene mesh is inert?
A. Yes, I do believe that.
Q. Doctor, did you review any documents, internal Ethicon documents, that their internal engineers determined that the polypropylene was not inert?
MR. SNELL: Object. Lacks foundation.
Go ahead.
THE DEPONENT: So I reviewed a variety of

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company documents, and I don't use company documents, generally, to base my opinions. Nor do I base my opinions on them entirely. I certainly consider them.

But polypropylene has been around for a long time not only in the form of mesh but also in the form of suture. And I believe that the -- that there is no resorption of the polypropylene and that it's -- it's safe and durable in the human application.

Q. (By Ms. Liu) And, Doctor, so are you saying that if you had seen a document of the internal engineers who tested the product and stated that it was not inert, you would not have relied on that document?

MR. SNELL: Object. Lacks foundation.

Go ahead.

THE DEPONENT: So I would have -- if I had seen a document like that, I would have considered it. But the term "inert" and "not inert" is very broad. And so if it was not inert, I would want to know, well, what are the clinical ramifications of this, right?

Autologous fascial slings are not inert. And yet, for a selected group of patients, they are a well-accepted form of stress incontinence surgery. So I -- I don't -- I wouldn't place undue weight on that document.

Q. (By Ms. Liu) Doctor, have you heard of a

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material called "ProNova"?

A. Does it have a different name? Is there a -- that sounds like a trade name. Is there is a generic name for it?

Q. Doctor, I'm just -- I'm just asking if you have ever heard of the term "ProNova"?

A. ProNova?

MR. SNELL: Object. Form.

Go ahead.

THE DEPONENT: I may have, but I don't recall off the top of my head.

Q. (By Ms. Liu) Do you remember reviewing any documents where, internally, the engineers were talking about moving the stress urinary incontinence mesh to using ProNova because of TVT's polypropylene not being inert?

MR. SNELL: Object. Lacks foundation.

THE DEPONENT: So I -- I recall reviewing company documents that talk about using a variety of meshes, in addition to the polypropylene -- polypropylene that's currently in use.

Again, I don't base my opinion on internal company documents that may be the result of academic dialogue in the design of something that is pre-clinical.

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Q. (By Ms. Liu) So, Doctor, you don't get involved in anything that is pre-clinical, correct?

A. Define "involved."

Q. You are not involved in anything -- designing any kind of products prior to it being released on the market, correct?

A. Correct.

Q. Your opinion is based on clinical studies and your own clinical practice, correct?

MR. SNELL: Objection. Misstates. And asked and answered about three or four other times.

THE DEPONENT: So, yeah, my clinical opinion is based on my own clinical experience, the available literature, as well as review of internal company documents.

So, whereas, I am not intimately involved prospectively in the design of something, certainly once I start using that product, I become familiar with salient points in the design.

Q. (By Ms. Liu) And, Doctor, you already stated that you don't -- you don't put much weight on the internal documents, right?

MR. SNELL: Objection. Probably misstates prior testimony. Also asked and answered.

THE DEPONENT: So I consider company

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documents, and I consider them in the context of all other available evidence about the TVT, as well as patient outcomes.

Q. (By Ms. Liu) Doctor, you mentioned sutures. How many sutures would equal a TVT sling?

A. That depends on the caliber and the length of the suture.

Q. Would you agree that the TVT sling has much more mesh fiber than a suture would, polypropylene fiber?

A. Than one single suture?

Q. Correct.

A. I would agree with it.

Q. And so if the product -- if a suture were to not be inert, the foreign body response would be much less than the amount that is in a mesh, correct?

MR. SNELL: Object. Incomplete hypothetical. Lacks foundation.

THE DEPONENT: I'm sorry. Can you repeat the question.

Q. (By Ms. Liu) Certainly.

So a suture has much less polypropylene fiber than a TVT mesh, correct?

A. Uh-huh.

Q. So if the polypropylene is determined to not

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be inert, if there is a foreign body reaction -- a long-term chronic foreign body reaction to the TVT or -- and to the suture, the amount of foreign body reaction would be much less with the suture; is that correct?

MR. SNELL: Objection. Lacks foundation. Also now compound.

THE DEPONENT: So if there were foreign --

MR. SNELL: I'm sorry. Incomplete hypothetical as well.

THE DEPONENT: If there were foreign body reaction to -- to any material, right? Since you are asking me a hypothetical, I will just answer it in regard to any material -- then you -- that could be a hypothesis that you could test, whether there's a dose response.

Q. (By Ms. Liu) Now, if there is -- let's assume that there is a chronic foreign body reaction, then the complications from a TVT mesh due to that foreign body reaction would be much greater than that of the suture; is that correct?

MR. SNELL: Objection. Lacks foundation. Misstates the evidence. Incomplete hypothetical.

THE DEPONENT: Right. So that's -- that's something that we do have, is the -- the clinical

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outcomes and the complications and, you know, pathologic data about the TVT and -- and those bear out that, actually, the -- the Prolene mesh performs very well in terms of clinical outcomes, not only -- you know, we are not talking about efficacy now. We are talking about safety, in terms of safety, that these reactions are incredibly rare.

Q. (By Ms. Liu) Doctor, could you turn to page 30 of your expert report.

Doctor, under the heading "TVT and prior anti-incontinence surgery," I wanted to get a clarification.

Are you stating that someone with a prior sling could be implanted with a TVT?

A. So this section refers to specific -- specifically to patients who have had a prior anti-incontinence procedure that's not specific to the sling.

Q. So let me clarify.

So this is only -- this -- this paragraph or this section only goes to patients that have had a non-sling anti-incontinence surgery?

MR. SNELL: No.

THE DEPONENT: No, no.

MR. SNELL: I'm sorry. Objection. Misstates

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her testimony.

THE DEPONENT: No.

Q. (By Ms. Liu) So that's what I wanted to clarify.

A. Yeah, it includes people who have had any anti-incontinence procedure in the past.

Q. So if somebody already has a TVT sling, it is your opinion that a second sling can be placed; is that correct?

A. Yeah, that's my opinion. Uh-huh.

Q. And that's after the first sling has failed, correct?

MR. SNELL: Objection.

THE DEPONENT: Generally, if someone has had a favorable outcome and has an effective anti-incontinence procedure, you wouldn't do another one, right? So you would have to have an indication for your repeat surgery, which would be recurrent or persistent stress incontinence.

Q. (By Ms. Liu) Now, Doctor, do you believe that Ethicon had tested the mesh material prior to marketing the product?

MR. SNELL: Objection. Form.

TVT, right?

MS. LIU: Yes, TVT. I'm just asking

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whenever -- let's assume that any question that I ask here, unless I specify otherwise, is about the TVT.

Okay?

MR. SNELL: Okay. So if you say "mesh," she can -- she can read that to be TVT mesh.

MS. LIU: Yes, absolutely.

MR. SNELL: Okay.

MS. LIU: Unless I specifically say pelvic organ prolapse mesh or some other mesh.

MR. SNELL: I just -- yes. I only have concern because we have talked about Ultrapro and other meshes already today, so -- but if she can -- I just want to make sure we have a clear record.

MS. LIU: Yes.

MR. SNELL: Can you repeat the question, then, so I understand -- I don't remember what it was.

(Record Read as follows:

"QUESTION: Now, Doctor, do you believe that Ethicon had tested the mesh material prior to marketing the product?")

MR. SNELL: Okay. Fair question.

THE DEPONENT: Yes. Ethicon tested the TVT mesh material before releasing the TVT to market.

Q. (By Ms. Liu) And do you know what tests

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those were?
A. There were a variety of tests. There were biomechanical tests that were done. There were biochemical tests that were done.
Yeah, I reviewed company documents with various tests.
Q. And do you know whether or not Ethicon tested multiple materials to see which one is the safest for patients?
A. So what I do know is that, in the design of the TVT, Petrus and Ulmsten tested a variety of materials, including, first, a removable implant and, later, Mersilene and Gore-Tex, and found that the polypropylene mesh was the best in terms of safety and efficacy.
Q. And would you agree that -- and we talked about this a little bit ago -- that if Ulmsten tested a product and it was a pay-for-performance compensation scheme, that that would put the results, you know, in a biased -- sorry. Let me repeat the question. This is a terrible question.
We talked a little bit about Ulmsten earlier, correct?
A. We did.
Q. And if Ulmsten had a pay-for-performance

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compensation scheme with Ethicon, would those results be questionable, in your mind?
MR. SNELL: Objection.
THE DEPONENT: So --
MR. SNELL: Asked and answered. I believe it also misstates the evidence or lacks foundation.
Go ahead.
THE DEPONENT: So Ulmsten wasn't paid for his own performance. My understanding of the arrangement between Ulmsten and Ethicon was that if his results were reproducible by others, that there would be an additional financial incentive. So his own results really didn't bear into that incentive.
Q. (By Ms. Liu) And, Doctor, when consultants have studies and papers and if they are highly paid consultants by mesh companies, does that conflict of interest go into your mind when you review those studies?
A. Yeah, I take that into consideration. I think we talked about that earlier.
Q. And you would give it less weight, correct?
MR. SNELL: Object. Misstates prior testimony.
THE DEPONENT: I wouldn't necessarily give it less weight. I would consider it. Again, we talked

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about all of the different characteristics of a study and its patient population that I -- that I consider when assigning weight to a study.
Q. (By Ms. Liu) You mentioned earlier that there was a study that refuted the degradation of polypropylene mesh.
Do you remember that?
A. I do.
Q. Was it the Thames study?
A. I don't remember the first author on that study. It was published recently.
Q. I believe you quoted it on page 41 of your report.
A. Oh, Thames. Okay. Yes, I was saying that name differently in my head. Yes. Thank you.
Q. I don't know how to pronounce it either. That was what I thought.
A. Yeah, like you are going with the river. I got it.
Q. Doctor, are you aware that Dr. Thames or "Thames," or whatever --
A. Sure.
Q. -- was a highly paid consultant for the mesh companies?
MR. SNELL: Object. Form.

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Go ahead.
THE DEPONENT: So I'm aware of his affiliation with a biomedical engineering consulting firm.
Q. (By Ms. Liu) And if the doctor had earned, you know, say, a million dollars from the mesh device companies, would that make his findings suspect to you?
A. So if I were to -- I don't know how much he was paid, obviously. But I can tell you this, that if his findings were somehow mis- -- either taken just completely in a void or were misaligned with the vast amount of clinical data that's out there about the short-, medium- and long-term outcomes of the TVT, it would certainly give me a very long pause.
The fact that his findings are supported completely by my own experience and the pooled experience of pelvic reconstructive surgeons internationally that are reporting their data makes that potential conflict of interest less concerning.
Q. And, Doctor, the other studies that are out there that show that mesh -- that mesh does degrade in vivo, have you discounted them because of Dr. Thames' study?
MR. SNELL: Objection.
THE DEPONENT: I don't think that --

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MR. SNELL: Lacks foundation as to -- go ahead.
Objection. Lacks foundation. Misstates the evidence.
THE DEPONENT: So in my opinion, there are no studies that definitively prove that mesh degrades, right?
Q. (By Ms. Liu) Okay.
A. There are studies that show that there are superficial artifact on electron microscopy. But as I mentioned in my general report, medical history is rife with these.
MS. LIU: Can we go off the record real quick, please.
(Recess taken.)
MS. LIU: Back on.
Q. (By Ms. Liu) Doctor, have you gone to a training session with Ethicon?
A. When I was a fellow, I attended an Ethicon-sponsored training session on electrosurgical energy and minimally evasive hysterectomy.
Q. Have you attended any TVT --
A. Training sessions?
Q. -- from Ethicon?
A. I have not.

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Q. Okay. Doctor, have you reviewed the TVT surgeons monograph?
A. I have.
Q. And, Doctor, have you reviewed professional education materials produced by Ethicon?
A. I have.
Q. And do you remember what they were?
A. So they were surgical videos. These I reviewed, actually, yeah, earlier, outside of this case, as well as presentations and slide decks.
Q. And do you know how long ago you reviewed them?
A. The -- just recently, except for the surgical video that I watched, you know, intermittently with residents and also in my fellowship.
Q. And it is your opinion that the surgeon's monograph and the presentations are sufficient; is that correct?
A. Yeah, I think they are very well done.
Q. Doctor, have you ever talked to anyone at Ethicon that felt that the laser cut mesh versus the mechanically cut mesh was a problem?
MR. SNELL: Object to form.
THE DEPONENT: I have never talked to anyone at Ethicon.

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Q. (By Ms. Liu) So you have never had any kind of communications with anyone at Ethicon?
A. Regarding the TVT legal proceedings, none.
Q. What about just regarding the TVT mesh?
A. You know, I may have had kind of social conversations as -- as a fellow with sales reps that covered the TVT product, but it wasn't about the TVT mesh specifically, no.
Q. Do you remember who your sales reps were?
A. No.
Q. Do you currently have sales reps?
A. No.
Q. So there are no sales reps that visit from Ethicon to your practice, currently?
A. Right. I can get in touch with them. There are ones that cover the area. But the way the contract purchasing works, there's really not a need for them.
Q. Have you ever seen internal documents from Ethicon that shows that physicians do not believe that the laser cut mesh versus the mechanically cut mesh are the same clinically?
MR. SNELL: Object. Lacks foundation.
THE DEPONENT: You know, I may have come across an email like that, but I don't -- I don't recall reviewing any reports of internal studies that

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concluded that there was a difference in the performance of this mesh at physiologic and -- outside of -- or within physiologic conditions.
Q. (By Ms. Liu) Do you know whether or not Ethicon has done a study comparing the laser cut mesh versus the mechanically cut mesh?
A. They do have laser cut and mechanically cut mesh, yes.
Q. My question was: Do you know if they have ever done a study?
A. So --
MR. SNELL: Object. Asked and answered. Go ahead.
THE DEPONENT: Yes, they have investigated the differences between mechanically cut and laser cut mesh.
Q. (By Ms. Liu) And do you know what the results are?
A. I do; that there's no difference under physiologic conditions.
Q. And have you seen the documents where it shows that the mechanically cut mesh is frayed upon forces that are placed on it?
A. Forces that greatly exceed anything that would be encountered under physiologic conditions.

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Q. And I know we talked a little bit about it, but do you know what the force is under a physiologic condition after implantation?
A. Yeah, that's -- that's widely known. People have studied those -- those forces. I would have to go -- I didn't memorize the exact number, but I can -- I can certainly find that for you, as can anyone who wants to do a PubMed search.
Q. So -- but you, off the top of your head, sitting here today, do not to know what that is; is that correct?
A. That is correct.
Q. Doctor, I want to talk to you a little bit about tensioning.
Would you agree that there is not a consensus between surgeons as to what the appropriate amount of tensioning is with the TVT?
MR. SNELL: Lacks foundation.
THE DEPONENT: No, I wouldn't agree with that statement. I think that there's a pretty uniform way in which tensioning is described both in operative reports and in the way that it is taught to trainees who are going to be performing the TVT.
Q. (By Ms. Liu) Now, as far as tensioning goes, there are terms such as "tension-free" or "no

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tensioning" or "no tension"; is that correct?
A. Those are terms that are used, yeah.
Q. And "minimal tension"?
A. Generally, "tension-free" is the term that is used.
Q. Okay. And so in that -- in that description, is there an exact amount of tension or how loose the sling needs to be for physicians to follow?
MR. SNELL: Objection. Compound.
Go ahead.
THE DEPONENT: So there -- there are suggestions for how to ensure a tension-free mesh placement, including placement of Mayo clamp or Mayo scissors or a Hegar dilator, all of which are going to ensure a tension-free placement.
Q. (By Ms. Liu) And what does "tension-free" mean?
A. "Tension-free" means that the material is not exerting tension or forces on -- on the urethra that's -- that's -- it's not a quantitative term. It's a qualitative descriptor, as often happens in --
Q. So you can't provide --
A. -- search --
MR. SNELL: Hold on. Don't interrupt her. Finish your answer.

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THE DEPONENT: That often happens in surgery, right?
So a great example is the Burch procedure. When you are placing your perivesical, periurethral sutures, you are then tensioning them to Cooper's ligament. And in doing so, the description is the right amount of tension, which is incredibly nebulous, you know. There is not anything to guide you about what instrument you use to ensure that. So a lot of it is -- is based on the surgeon's training and clinical experience.
Q. (By Ms. Liu) And, Doctor, you reviewed many studies. I want to talk a little bit about erosions or exposures.
Have you seen some studies with erosion rates as high as 19 percent?
A. Specific to the TVT?
Q. Correct, the mid-urethral sling.
MR. SNELL: Hold on. Objection. Foundation.
Are we talking TVT or mid-urethral sling?
MS. LIU: Mid-urethral slings.
MR. SNELL: So she's talking about beyond TVT, so answer whatever you know.
THE DEPONENT: Yeah, I have seen studies, for example, of the ObTape or the IVS Tunneller that have

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very high, relative to the TVT, extrusion rates.
Q. (By Ms. Liu) Have you seen high rates of erosion specific with the TVT?
A. And by "erosion," are we talking about in viscous, so urethra, bladder, bowel?
Q. Let's go with erosion meaning eroding into the vaginal tissues -- or let's do extrusion, erosion and exposure together.
A. Okay.
MR. SNELL: Object. Form. Compound.
Go ahead.
THE DEPONENT: So in synthesizing my opinion about mesh erosion specific to the TVT, I have looked at many studies with specific weight that I have placed on the systematic reviews, the Cochrane reviews, because they are the most likely to capture complications and complications rates, because of the pooled end for the study.
And -- and those have come back, you know, both in time and regardless of author, with roughly the same conclusions; that those erosion rates are less than 3 percent.
Q. (By Ms. Liu) And do you disagree that the Ethicon president, Renee Salman, had said that the TVT erosion rate was 5 to 6 percent?

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MR. SNELL: Objection. Misstates the evidence.
THE DEPONENT: So if someone said that the TVT erosion rate is 5 to 6 percent, I would disagree with that statement.
Q. (By Ms. Liu) Okay. You would or wouldn't?
MR. SNELL: She would.
THE DEPONENT: I would.
MR. SNELL: Asked and answered.
THE DEPONENT: I would. That's not corroborated by the data.
MS. LIU: I am going to save the rest of my time for rebuttal.
Let's go off the record.
(Recess taken.)
EXAMINATION
BY MR. SNELL:
Q. Dr. Ramm, this is Burt Snell representing Ethicon and Johnson & Johnson. I have some follow-up questions based on the questions posed by plaintiffs' counsel.
Are you ready to proceed?
A. I am ready.
Q. Okay. And the same instructions plaintiffs' counsel gave you earlier apply. So if you don't

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understand one of my questions, just let me know and I will try to give you questions that you can answer.
A. Will do.
Q. You were asked earlier about all the different ways you track your outcomes, complications, efficacy with regard to the TVT device.
Do you recollect those lines of questioning?
A. I do.
Q. And you just talked about your practice, residency, things like that.
Let me ask you this: Did you track your TVT surgical outcomes in fellowship?
A. Yeah, we tracked those very carefully. So I did fellowship at Loyola University Medical Center, which was at the entire duration of my fellowship, a site in the pelvic floor disorders network. So patients were very carefully tracked, and those outcomes were reported in -- in the trials that we participated in.
Q. Can you tell us some of those trials where your patients, and the patients who you were involved in implanting or following TVT, what -- this is a terrible question. Rephrase.
Can you tell us the names of those studies that you were involved in where you either implanted or

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you followed patients who received a TVT retropubic device --
A. Sure.
Q. -- for your fellowship.
A. For my fellowship.
Q. Yes.
A. So during my fellowship with the PFD -- and specifically we participated in the OPUS trial, which is the trial of prophylactic anti-incontinence procedures in patients without symptomatic stress urinary incontinence at of time of vagina apical repair, and those outcomes were followed and there were no mesh exposures in -- in that group. Obviously, none in the sham group either.
Q. Let me ask you a question --
MS. LIU: Well --
Q. (By Mr. Snell) -- was that a small study, or how would you characterize the OPUS trial? What type --
A. That was a study --
Q. -- of study was it?
MS. LIU: Objection. Form.
MR. SNELL: Sorry. Withdraw.
Q. (By Mr. Snell) What type of study was the OPUS trial with regard to its design?

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A. So the OPUS trial was a randomized clinical trial that was multi-centered and involved over nine centers nationally.
Q. Is that a -- well, go ahead. I'm sorry.
I was going to ask, is that a level-1 evidence trial?
A. Yeah, it is.
Q. Okay.
A. The OPTIMAL trial was another randomized surgical, multi-centered study that examined outcomes following uterus, sacral and sacrospinous ligament suspension, but many of those patients had a concomitant TVT, and those results were reported.
MS. LIU: Let me -- I'm sorry. I just didn't hear.
What was the name of that trial?
THE DEPONENT: OPTIMAL, O-P-T-I-M-A-L.
Q. (By Mr. Snell) You mentioned mesh exposures in the OPUS trial.
Was that tracked in the OPTIMAL trial?
A. It was tracked in the OPTIMAL trial and -- yeah.
Q. Was the rate of mesh exposure in the TVT patients -- let me ask you this: In the OPTIMAL trial, how many patients was that? Was that under 100? More

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than 100?
Just a general neighborhood.
A. More than 100 patients.
Q. And the rate of mesh exposure, was it consistent or inconsistent with the rates you mentioned earlier to plaintiffs' counsel, less than 3 percent?
MS. LIU: Objection. Form.
THE DEPONENT: It was consistent with that rate.
Q. (By Mr. Snell) Do you have a recollection as to what the exact number was, or the range, if you can give us?
A. Yeah. I believe it was 1-1/2 to 2-1/2 percent.
Q. Okay.
A. And then also, when I was there, we were a center of the urinary incontinence treatment network. So we participated in patient recruitment for the TOMUS trial, the trial of mid-urethral slings, which compared the retropubic to the transobturator approach, and the retropubic approach was represented entirely by the TVT sling.
And so I'm sure you are familiar with the complications, papers following that trial.
Q. And for your opinion with regard to the

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safety and efficacy of TVT, do you rely on not just your education, training and clinical experience, but also these study results that you just talked to us about, OPUS, OPTIMAL and TOMUS, with regard to the TVT device?
MS. LIU: Objection. Form.
THE DEPONENT: Yeah, I -- I rely on -- on these studies and -- and then these results, actually, and these studies reflect our practice as well.
Q. (By Mr. Snell) Okay. Did you track your outcomes and surgeries in connection with any of your board examinations or preparation?
MS. LIU: Objection. Form.
THE DEPONENT: So I had to provide a case list for my general boards, and I had to provide a case list for the written FPMRS boards as well and state the procedure and complications thereafter.
Q. (By Mr. Snell) Do you -- have you systematically tracked your own complications and outcomes with regard to TVT, since the time of your fellowship?
A. I have. So in my own practice, I -- I track complications and -- and results at a year after -- you know, including and up to a year after surgery.
Q. And did you -- do you use your tracking of

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your own complications or efficacy in informing your discussion with patients as to potential risk or benefits with the TVT device?
A. So when I counsel them, the patients, I -- I take the approach of this is -- this is the body of literature, the data that guides my decision, and my own personal experience is corroborated -- is supported by this -- by this data.
Q. Okay. At page 2 of your report, you note that you were trained on and have used the Ethicon TVT-O device for stress incontinence.
Do you see that?
A. I do.
Q. Can you tell us, was that in residency or fellowship, or when did that occur?
A. Both residency and fellowship.
Q. Okay. Are the rates of exposure that were reported in the OPUS and OPTIMAL trial, for example, consistent or inconsistent with your own personal experience that you have systematically tracked --
MS. LIU: Objection.
Q. (By Mr. Snell) -- since your fellowship?
MS. LIU: Objection. Form. Compound.
THE DEPONENT: So I would say that my own personal rates are a little bit lower than what is

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reported in these trials, and I think that's a function of a couple factors.
Q. (By Mr. Snell) You were asked questions about the various different IFUs you looked at, and you were also asked questions about whether you reviewed the TVT monogram.
Do you recollect that?
A. Yeah.
Q. You brought numerous binders and materials here today; is that correct?
A. Yes.
Q. And you have looked at the materials and the binders and whatnot; is that correct?
A. That's correct.
Q. So there's a binder that has the monograph and it has also got a TVT IFU in it.
Is this an IFU that you reviewed?
A. Yes.
Q. And do you recall if this IFU was from around this same time period as the surgeon's monograph in the early 2000s?
MS. LIU: Objection. Form.
THE DEPONENT: I believe so. They were filed together.
Q. (By Mr. Snell) You talked about reviewing

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numerous different company documents on different topics.
Do you recall that?
A. Yes.
Q. Did you also look at company documents that plaintiffs' experts cited to or that were discussed in their depositions that you reviewed?
A. I did.
MS. LIU: Objection. Form.
Q. (By Mr. Snell) And did you consider those company documents?
A. I looked at them and considered them, yes.
Q. And is it correct that you have Dr. Rosenzweig's and Dr. Blaivas' depositions with all their exhibits and binders here?
A. That's correct.
Q. Did you read their -- the exhibits to the plaintiffs' experts' depositions?
A. I did. I read those binders.
Q. Okay. Did you review studies concerning the pathological analysis of the TVT?
MR. SNELL: Objection. Form. Vague.
THE DEPONENT: So I reviewed studies that were based on pathologic findings after mesh implantation.

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Is that what you are referring to?
Q. (By Mr. Snell) Yes.
You were asked questions about ProNova and Ultrapro.
Do you recall those questions?
A. Yes.
Q. Did you investigate whether there was a safer alternative mesh for the TVT device as opposed to the Prolene polypropylene mesh?
A. Yes. I investigated this.
Q. Did you issue an opinion on that?
A. Yeah, I believe that the -- the TVT polypropylene mesh is the safest mesh for the application of surgical treatment of stress urinary incontinence.
Q. With regard to meshes like Ultrapro, did you also read or see any studies with regard to another prolapse mesh called BiPro?
A. Yes. It also has absorbable component.
Q. And did you see whether or not those meshes like Ultrapro and BiPro have a risk of mesh exposure with their use?
A. They do. And that risk is actually higher than the heavier weight relative to the Ultrapro or BiPro polypropylene mesh.

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Q. Does that inform your opinion with regard to the TVT device employing the Prolene polypropylene mesh?
MS. LIU: Objection. Form.
THE DEPONENT: So it supported my opinion that the TVT polypropylene mesh that is currently in use is the safest and the best alternative.
Q. (By Mr. Snell) Did you review any internal documents that discussed studies done with a lighter-weight, partially absorbable mesh for the sling application and whether that sling was able to be effectively used in cadavers?
MS. LIU: Objection. Form.
THE DEPONENT: Yes. So those were studies about the Ultrapro mesh which has an absorbable monocryl component, and those -- those early-phase studies show that the outcomes -- not the clinical outcomes but, rather, the implantation outcomes were not satisfactory in cadavers.
Q. (By Mr. Snell) Are you an expert in assessing the design of the TVT device?
MS. LIU: Objection. Asked and answered.
THE DEPONENT: I believe that I'm an expert. I have implanted well over 1,000 TVT devices.
Q. (By Mr. Snell) Did you investigate the

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design and the development of TVT in formulating your opinions?
A. I did. It's outlined in my report. I looked at the integral theory that Ulmsten and Petrus outlined and read about the different steps that they took in the development of the TVT that ultimately led to their arrival at the product that -- that we are using today.
Q. Did you evaluate whether or not different materials were assessed in the design of the TVT?
A. Yeah.
MS. LIU: Objection. Form.
THE DEPONENT: We -- I think we discussed this a little bit earlier, but there was an animal model, as -- as well as experiments in humans, that they used a variety of meshes -- Gore-Tex, Mersilene, Marlex -- and polypropylene had the best side effect and safety profile.
Q. (By Mr. Snell) Are you an expert in the utility, feasibility and effect of the different design elements of the actual TVT device --
MS. LIU: Objection. Form.
Q. (By Mr. Snell) -- to include the trocar, the sheath and the mesh?
MS. LIU: Objection. Form. Compound.
THE DEPONENT: Yes, I believe that I am. I

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utilize and evaluate these different components regularly.
Q. (By Mr. Snell) Did you assess and study the medical literature with regard to those design elements of the TVT device?
A. I did.
Q. Are those different design elements evaluated -- you mentioned Dr. Petrus and Dr. Ulmsten.
Are they pelvic floor surgeons as well?
A. Yeah, they are, Swedish and Australian.
Q. You were asked some questions about whether you would disagree with someone at Ethicon who said X, Y or Z.
Do you recall those general hypothetical questions?
MS. LIU: Objection. Form. Vague.
THE DEPONENT: I think, yeah.
Q. (By Mr. Snell) Well, let me ask you this: Are you more interested in what data proves as opposed to what a study author or someone may say?
MS. LIU: Objection. Form.
THE DEPONENT: So I do my very best to evaluate the data objectively and to draw my own conclusions. So the results section of a paper and the method sections are probably the most informative.

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Q. (By Mr. Snell) Was one of the meshes that you saw assessed in -- with regard to -- strike that. Back up.
Was one of the meshes that you saw assessed or discussed in the company documents a mesh called "PVDF"?
A. Yes, I have heard of this mesh.
Q. Are you aware of anybody in the United States who uses PVDF mesh for the stress urinary incontinence application?
A. No, it's not used for that application, and it's not used in the United States.
Q. Plaintiffs' counsel asked you about, if I recall correctly, whether you -- let me find it.
Let me ask you this: You earlier mentioned in your testimony that you didn't need to do a certain activity because that information had already been assessed and was known in your field?
A. Oh, like counsel Ethicon on the pore size?
Q. Right.
A. Yeah.
Q. Do you have an opinion as to what is the optimal pore size for the TVT device?
A. Greater than 75 microns, which would then place it into the category of type 1 monofilament mesh.

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Q. And for the Prolene polypropylene mesh used in the TVT, is it the optimal mesh based on the reliable clinical evidence that you reviewed?
MS. LIU: Objection. Form.
THE DEPONENT: Yes, it is. I believe that it is.
MR. SNELL: That's all I have.
MS. LIU: Let's go off the record real quickly.
(Recess taken.)
MS. LIU: Back on.
FURTHER EXAMINATION
BY MS. LIU:
Q. Doctor, your -- defense counsel asked you about your tracking the outcomes during your fellowship. You mentioned the OPUS trial.
That was a prophylactic trial of mid-urethral slings; is that correct?
A. Yes. So the premise of the trial is that when you correct pelvic organ prolapse, you can unmask stress urinary incontinence that was previously undiagnosed, and so the -- the point of the trial was to compare whether a prophylactic mid-urethral sling for the treatment of stress urinary incontinence was warranted.

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Q. And, Doctor, you mentioned that there were no mesh exposures.
Was that the only complication you tracked with regard to the TVT in this trial?
A. No. No. That was one of them. Urinary retention, urinary tract infection rate, re-operation, you know, a number of them. I -- I we can look at the complications table for -- for that study, if you would like.
Q. Doctor, do you know whether or not it tracked -- strike that.
Doctor, how long was this study for?
A. So there's one-year and two-year data available, and those -- those patients are still being followed. So it's hard to know what the pelvic floor disorders network will decide to publish, but my understanding is that they're still -- the patients are still being tracked.
Q. In this one- and two-year data, does it track chronic pain?
A. I would have to look at the complications table. I can't remember off the top of my head.
Q. Do you know whether or not it tracks dyspareunia, chronic dyspareunia?
MR. SNELL: Object. Form.

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THE DEPONENT: Again, the same answer.
Q. (By Ms. Liu) And, Doctor, this OPTIMAL study that you also talked about, you also talked about mesh exposures with your counsel over there.
Did you also track chronic pain in this study?
MR. SNELL: Objection in reference to me as her counsel.
MS. LIU: Sorry.
MR. SNELL: That's okay.
THE DEPONENT: So the OPTIMAL trial was -- had several arms, including one that looked at pelvic floor physical therapy, so pelvic floor muscle performance was tracked. And even if the -- the pain-related validated questionnaires and the sexual function questionnaires aren't included in that paper, I think it was tracked. It's not published. But that there may be a secondary analysis. Oftentimes there's -- there's secondary analyses and smaller papers that come out of these trials.
Q. (By Ms. Liu) So when something is not published, like a specific complication is not published and it's included in a meta-analysis, the portions that aren't published can't be included in that meta-analysis; is that correct?

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MR. SNELL: Objection. Foundation. Incomplete hypothetical.
THE DEPONENT: So meta-analyses generally include published data, yes.
Q. (By Ms. Liu) And so if it's not published, it would not be included, correct?
A. So in this case that you're asking specifically, it would change the denominator, the end, right? So if you are not reporting on a number of patients -- if you are not reporting on pain or dyspareunia, in general, then you are not changing the number of patients who did or didn't have pain. You are -- you simply have a lack of information, and that drives down your total number from which you can draw conclusions.
Q. And how long was this OPTIMAL study?
A. So it -- again, it is still ongoing, but the one-year outcomes have been published and maybe the two-year outcomes. I got to check.
Q. And the TOMUS trial, that was a one-year study, correct?
A. No. That trial is ongoing as well. And two-year outcomes are actually the ones that are reported in the complications paper, which is one of the secondary papers from that trial.

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Q. Now, were the primary outcomes of all three of these studies cure rate or efficacy?
MR. SNELL: Objection. Form.
THE DEPONENT: The primary outcome of the TOMUS trial was non-inferiority of the transobturator approach as it relates to the retropubic approach, which was deemed the standard of care.
Q. (By Ms. Liu) And that was an equivalent study -- the equivalent study, correct?
A. That was a non-inferiority study.
Q. Okay.
A. And the primary outcome for the -- for the OPUS trial was actually the number needed to treat with regard to placement of a mid-urethral sling into an asymptomatic patient to prevent one case of de novo stress urinary incontinence. The primary outcomes in the OPTIMAL trial were anatomic outcomes for prolapse repair.
Q. And, Doctor, do you still place TVTs prophylactically?
A. So I present the options to the patients, and I believe in shared decision-making that's based on a patient's individual goals. I -- if someone strongly feels that they want to avoid any risk of stress incontinence or any risk of having to be re-operated

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for stress incontinence, then I don't think it's unreasonable, as long as the patient understands that she's taking on the risks of the mid-urethral sling in the absence of knowing for sure that she would have needed the procedure.
Q. In general, do you recommend implanting a TVT sling prophylactically with a patient that you are treating surgically for a pelvic organ prolapse?
A. I offer it, but I don't recommend it. Again, it's a process of shared decision-making. And it depends very much on the patient and -- and her goals.
Q. And, Doctor, you stated that you do track your complications up to a year of your current patients, but you don't track further down past a year, correct?
A. Not -- not systematically, in the sense that the patients don't -- aren't required to follow up with me after a year. But as I previously mentioned, I'm fortunate to practice within a system that's -- that's closed. So if a patient showed up within the Kaiser northern California system later on down the line, I would be privy to that information.
Q. And that's -- that's a patient here or a patient there, it's not necessarily all of your patients, correct?

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MR. SNELL: Object. Form.
THE DEPONENT: A patient here or there with regards to what? I'm sorry.
Q. (By Ms. Liu) Past the one-year mark, if a patient goes to someone else to -- within Kaiser, you might hear about it, but it's not something that you actively track; is that correct?
MR. SNELL: Object. Form.
THE DEPONENT: So I don't actively pro- -- prospectively track outcomes beyond a year.
Q. (By Ms. Liu) Doctor, these binders that are on the table currently, did you put them together?
A. No, I didn't originally put them together.
Q. Do you know who put them together?
A. I imagine the associates at Butler Snell.
Q. They were put together by the attorneys, correct?
A. Correct.
Q. So it wasn't that you looked at each document or looked at each article and put them together as something that you have reviewed; is that correct?
MR. SNELL: Objection. Misstates and compound.
THE DEPONENT: So I have reviewed all of the documents that are -- that are -- that were presented

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here. I didn't print them out. I didn't put them in the binders.
Q. (By Ms. Liu) Did you read each and every page of those documents in the binders?
MR. SNELL: Objection. Asked and answered.
THE DEPONENT: Yes.
Q. (By Ms. Liu) In thorough review?
MR. SNELL: Objection.
THE DEPONENT: I looked -- I looked at all of them. There's -- there are duplicated records in there. There are also studies that I was previously familiar with, so I didn't read every single word.
Q. (By Ms. Liu) Now, defense counsel also asked you about the exhibits for the expert reports that you had read, Dr. Blaivas and Dr. Rosenzweig.
Do you remember that questioning?
A. Yes.
Q. Did you specifically look up every footnote or every citation within those reports?
A. I looked up the citations that I thought were particularly relevant or that were new to me that I was unfamiliar with.
Q. Doctor, did you read any documents from Ethicon that specifically stated that they believed the Amid classification was outdated?

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A. There's been -- so there's been discussion in the pelvic reconstructive surgery community about whether it is outdated; however, it's currently, and in the foreseeable future, still the accepted classification system when describing mesh.
MS. LIU: I believe that's all the questions that I have currently.
MR. SNELL: Just a couple questions.
FURTHER EXAMINATION
BY MR. SNELL:
Q. So you were asked about the prophylactic placement of TVT.
Do you recall that?
A. Yes.
Q. In your expert report, you cite to the recent updated practice bulletin by ACOG and OGs regarding stress urinary incontinence.
Do you recollect that?
A. Yes.
Q. Is the prophylactic placement of the TVT device supported by or recognized as within the standard of care by ACOG and OGs in the most recent practice bulletin?
A. Yes. So I -- the -- the conclusion, based on the available data, is that this is something that

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should be discussed with the patient and offered on an individual basis after a thorough discussion of the potential risks and benefits.
Q. Is that an assessment you have independently analyzed and made and offered to your patients?
A. Which assessment?
Q. Withdrawn.
You were asked about the Amid classification.
Is the Amid classification based upon biologic plausibility?
MS. LIU: Objection. Form.
THE DEPONENT: So the Amid classification is -- is, to some extent, based on that. But it is also based on clinical outcomes with the -- with the materials that fall into these different categories.
Q. (By Mr. Snell) Are all opinions and bases for opinions that you stated or discussed with counsel here today been given to a reasonable degree of medical certainty?
A. Yes, they are.
MR. SNELL: No further questions.
MS. LIU: I don't have any questions, but I would like, for housekeeping's sake, to state on the record that I am marking the thumb drives as Exhibits 7 through 10 -- actually, no, 7 through 12.

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THE DEPONENT: There's six of them.
MS. LIU: 7 through 12.
MR. SNELL: Okay. And I will just note for housekeeping that there are an additional -- one, two -- three hard-copy binders, a minimum of five or six spiral-bound binders, and stacks of company documents, studies and other materials the doctor has reviewed that are not being marked.
MS. LIU: We can mark them, if you would like, but that's just --
MR. SNELL: No, no, no. It's your deposition. It's your cost, if you want to mark them; however, I'm making a record because this is the only TVT general deposition this witness -- right? -- is doing. So I don't want there to be some claim that she didn't present and bring her file on TVT to a deposition.
MS. LIU: Now --
MR. SNELL: It's all there.
MS. LIU: -- I just want to --
MR. SNELL: As between all the thumb drives and all her hard-copy materials, everything -- everything is on there or -- and/or the materials listed.
That reminds me, I do have one other

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question.
FURTHER EXAMINATION
BY MR. SNELL:
Q. Doctor -- sorry. I should ask this, but have you reviewed any of the recent studies that have just come out at SUFU with regard to whether there is any type of adverse clinical inflammatory or autoimmune response with the use of mesh?
A. Yeah, there are two abstracts that were presented at SUFU that should be available for publication soon that are epidemiologic studies based on the New York State population following the incidence of cancers, as well as autoimmune diseases.
Q. Okay.
A. And there was actually a lower incidence of bladder cancers in patients who had had prior mesh implantation and no difference in the incidence of autoimmune diseases.
Q. So I guess, then, my question would be: Do those new studies -- do they -- supportive of your opinions you have expressed in your report or not?
A. Yeah, I think they fall exactly in line with my opinion that the TVT is a safe device that's effective in the treatment of stress urinary incontinence with very minimal short-term, medium-, or

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long-term risk.
Q. Do those studies cause you to change any of your opinions?
A. They do not.
MR. SNELL: Okay. That's all I have.
(Exhibit 7 was marked for identification by the court reporter and is attached hereto.)
(Exhibit 8 was marked for identification by the court reporter and is attached hereto.)
(Exhibit 9 was marked for identification by the court reporter and is attached hereto.)
(Exhibit 10 was marked for identification by the court reporter and is attached hereto.)
(Exhibit 11 was marked for identification by the court reporter and is attached hereto.)
(Exhibit 12 was marked for identification by the court reporter and is attached hereto.)
MS. LIU: I just have one -- another housekeeping thing.
MR. SNELL: Uh-huh.
MS. LIU: I know you had a bag of the -- the thumb drives and some of them were --
MR. SNELL: Right there.
MS. LIU: Some were case specific and some of were not, more general.

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MR. SNELL: She separated all of them.
MS. LIU: Right. I just want to make sure that there were none that were in the -- in the bag that is general that was left as general that --
MR. SNELL: You can answer that. I thought you went through --
THE DEPONENT: Yeah --
MR. SNELL: These are all case specific.
THE DEPONENT: -- I can go through them again, if you want me to. They are going to have the case --
MS. LIU: Okay. I just want to double-check --
MR. SNELL: So Dr. Bales, that's got the -- that's in the case, Galarza, Moore.
THE DEPONENT: Deposition, Moore.
MR. SNELL: Moore is the case, right? Brown? Moore?
THE DEPONENT: Yeah, that's the case.
MR. SNELL: Katherine Moore?
THE DEPONENT: Yeah, Moore deposition.
MR. SNELL: It's hard to read.
THE DEPONENT: Galarza.
MR. SNELL: Galarza. So these are all case specific. You have all the generals.

MS. LIU: Okay. And I just want to clarify very quickly that all of the materials that are in the binders are in the thumb drives; is that correct?

MR. SNELL: You are asking me or the witness?

MS. LIU: Whoever put them together, at this point.

MR. SNELL: I don't know.

THE DEPONENT: I don't know that they are exact duplicates of each other, actually.

MR. SNELL: I don't either. I can't say that either.

THE DEPONENT: I don't know the answer to that.

MS. LIU: Just on the record, Doctor, these thumb drives are not put together by you, correct?

THE DEPONENT: Correct.

MS. LIU: Okay. They were given to you by Butler Snell, correct?

THE DEPONENT: Correct.

MS. LIU: That's it. No further questions.

(Deposition concluded at 1:14 p.m.)

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I, OLGA RAMM, M.D., do hereby declare under penalty of perjury that I have read the foregoing transcript; that I have made any corrections as appear notes; that my testimony as contained herein, as corrected, is true and correct.

Executed this ____ day of _____, 2017, at _____, _____.

_____

OLGA RAMM, M.D.

STATE OF CALIFORNIA) ss:
)
COUNTY OF CONTRA COSTA)

I, Rebecca L. Romano, CSR. 12546, do hereby certify:

That the foregoing deposition testimony was taken before me at the time and place therein set forth and at which time the witness was administered the oath;

That the testimony of the witness and all objections made by counsel at the time of the examination were recorded stenographically by me, and were thereafter transcribed under my direction and supervision, and that the foregoing pages contain a full, true and accurate record of all proceedings and testimony to the best of my skill and ability.

I further certify that I am neither counsel for any party to said action, nor am I related to any party to said action, nor am I in any way interested in the outcome thereof.

IN WITNESS WHEREOF, I have subscribed my name this 22nd day of March, 2017.

_____
Rebecca L. Romano, RPR,
CSR. No 12546

DEPOSITION ERRATA SHEET

Case Name: In Re: Ethicon, Inc. Pelvic Repair System Products Liability Litigation
Name of Witness: Olga Ramm, M.D.
Date of Deposition: March 17, 2017
Job No.: 152305
Reason Codes: 1. To clarify the record.
2. To conform to the facts.
3. To Correct transcript errors.

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_____ Subject to the above changes, I certify that the transcript is true and correct

_____ No changes have been made. I certify that the transcript is true and correct.

_____

OLGA RAMM, M.D.